A Fix for Airway Management Training?

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Realism and Suitability of the Fix for Life Cadaver Model

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A Fix for Airway Management Training?

Realism and Suitability of the Fix for Life Cadaver Model

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aan de Vrije Universiteit Amsterdam,
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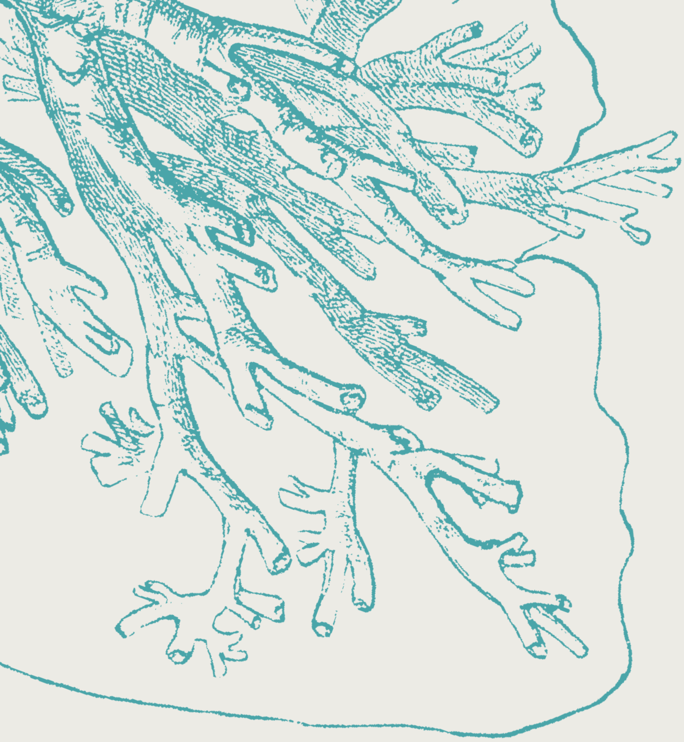
“Nothing is more difficult,
and therefore more precious,
than to be able to decide.”

Napoleon Bonaparte

Voor mammaloes

Contents

Chapter 1	General introduction	9
Chapter 2	Comparison of a novel cadaver model (Fix for Life) with the formalin-fixed cadaver and manikin model for suitability and realism in airway management training	21
Chapter 3	Suitability and realism of the novel Fix for Life cadaver model for videolaryngoscopy and fibreoptic tracheoscopy in airway management training	39
Chapter 4	Cricothyroid membrane identification with ultrasonography and palpation in cadavers with a novel fixation technique (Fix for Life): a laboratory investigation	55
Chapter 5	Comparison of videolaryngoscopy alone to video-assisted fibreoptic intubation in a difficult cadaver airway model	73
Chapter 6	Summary and general discussion	89
Chapter 7	Nederlandse samenvatting	109
Appendices	Co-authors and affiliations	121
	Dankwoord	123
	Curriculum vitae	129



CHAPTER 1

General introduction

Background

Airway management is an important component in the medical specialty of anesthesiology and related fields, such as intensive care and emergency medicine. The instruction of anesthesiologists-to-be in the various techniques of airway management is a crucial element of the postgraduate medical training program. Essential and more advanced skills to master include facemask ventilation, direct laryngoscopy, videolaryngoscopy, flexible fibreoptic tracheoscopy, laryngeal mask insertion, and cricothyroidotomy.[1]

In more detail, facemask ventilation refers to the ventilation with a mask sealed around the patient's nose and mouth, usually connected to a self-inflating bag. With the application of pressure on the self-inflating bag, the patient's lungs are ventilated (figure A).

Tracheal intubation by direct laryngoscopy is the use of the laryngoscope, a usually left-handed angulated blade, to move the patient's tongue to the side while the glottis is visualized. Subsequently, an endotracheal tube is inserted under direct vision through the vocal cords of the patient (figure B).

In videolaryngoscopy a laryngoscope with a camera in the tip of the blade is employed. This allows for an indirect view of the oropharyngeal cavity and glottis of the patient on a video screen (figure C).

Flexible fibreoptic or video tracheoscopy is the technique in which a flexible endoscope with a camera in the tip, and with an endotracheal tube pre-fixed on the scope, can be manipulated in different directions via a control in the handle. Through subtle movements of the endoscope within the patient's oropharyngeal cavity, the vocal cords and trachea are approached (figure D). To better distinguish this technique from videolaryngoscopy, we also use the term 'fibreoptic intubation' in this thesis.

A laryngeal mask is an airway device which creates an airway on the anatomical level just above the laryngeal inlet. Hence it is also classified as a supra-glottic or extra-glottic airway device. It seals and separates the laryngeal inlet by an oval cuff against the pharynx, so that a relatively secure airway can be achieved. The laryngeal mask is inserted through the oral cavity and placed on the laryngeal inlet (figure E).

Finally, in the exceptional case of a 'can't intubate can't oxygenate' situation, it is of importance to correctly identify the cricothyroid membrane in order to perform a cricothyroidotomy, the ultimate life-rescuing option. Via an incision at the front of the neck of the patient, as well as through the cricothyroid membrane, an endotracheal tube is inserted in the patient's airway (figure F).[2] The identification of the correct location for cricothyroidotomy is usually done by palpation of the patient's neck, although ultrasonography is described as being more accurate in locating the cricothyroid membrane.[3]

Training of the majority of these techniques has traditionally been on real patients, e.g., undergoing anesthesia in the operating room. In more recent years, other training modalities have become available. These include synthetic manikins or models, simulator models, and virtual models.[4, 5] An example of a widely used synthetic manikin is the SimMan 3G (SimMan 3G®; Laerdal Medical®), a full body synthetic manikin, generally used for training in resuscitation methods. The head of this manikin is utilized for training in, for example, facemask ventilation and tracheal intubation. Because of computerized control, the SimMan 3G is especially useful for simulation training, in which the manikin is able to continuously provide information on physiological or neurological parameters. Numerous other models and manikins are available on the market. An example of a virtual simulator is a virtual reality airway simulator, on which trainees can practise bronchoscopy (e.g., the ORSIM® bronchoscopy simulator). While handling the bronchoscope in these types of training devices, all internal anatomical views are computerized images, thus supplying a virtual reality.

It has been reported that these models are helpful in acquiring the necessary skills. However, there is an ongoing discussion on how realistic a model should be.[6-8] A model that is very realistic with regard to mimicking the look and feel of a real patient could be preferable, as this combines the most realistic anatomical environment while learning the airway management technique. Recently deceased patients can provide for this realistic anatomical experience and have also been used to train and teach techniques, e.g., tracheal intubation. However, the use of recently deceased patients raises ethical concerns, especially because of lack of consent of the deceased.[9]

The utilization of cadavers of body donors, i.e., donors who donated their body out of their own free will after death to an anatomical institution, is not limited by these aforementioned ethical constraints. The cadavers of these body donors are usually embalmed to stop decomposition and are often used to teach medical students human clinical anatomy.[10] In addition, the cadavers are used in postgraduate medical teaching, such as the instruction of surgical procedures to surgeons in training. In the traditional embalming method used in many anatomical institutions, the embalmment fluid contains formaldehyde. Formalin-fixed cadavers, while optimal conservation is achieved because of the formaldehyde, have the disadvantage of becoming rigid or hard-fixed. Moreover, the use of formaldehyde has safety issues. Evaporation of formaldehyde causes irritation to the skin, mucous membranes of the eyes, throat and airways, and exposure to large concentrations during prolonged periods is associated with nasopharyngeal cancer.[11] Alongside the formaldehyde based embalming method, numerous other conservation methods are used worldwide, while providing for a more flexible cadaver model. These so called soft-fixed methods include, for example, Thiel, Anubifix, Gluteraldehyde, and Ethanol-Glycerine embalming.[10] A disadvantage to some of these embalming methods is the shorter duration in which the cadaver model can be used before further putrefaction sets in, for instance after several weeks.

Another option to provide for the most flexible tissue experience, is to utilize the so named fresh frozen cadaver. These cadavers of body donors are frozen after arrival at the anatomical institution, and are thawed before use in an educational session in the dissection room. Because of the flexibility of the tissues, this type of cadaver model is particularly appropriate for postgraduate surgical training. A major disadvantage of fresh frozen cadavers is that after thawing the decomposition continues. This restricts the timeframe in which the human material can be used, usually limited from several hours to several days.

Recently, a new embalming method has been developed with allegedly the same properties in tissue quality and flexibility as fresh frozen cadaver models, but without the disadvantages of ongoing decomposition. This embalming method is named 'Fix for Life' (F4L).[12] In this embalming technique only minimal amounts of formaldehyde are used, thus limiting the rigidity of the tissues and the hazardous properties. In addition, the risk of exposure to pathogens is also effectually minimalized. The exact formula is proprietary knowledge, but supposedly not harmful to mortuary staff when used properly and in accordance with the prescribed procedures. The F4L embalming method is reportedly the result of several years of research into conservation techniques. It was developed under supervision of Andries van Dam, conservator of the Anatomical Museum (Anatomisch Museum, Leiden) and in close collaboration with the Department of Anatomy and Embryology of the Leiden University Medical Centre. It is commercially available to departments of anatomy worldwide.[13]

The F4L embalmment of the cadaver would allow for multiple dissection or surgical procedural training sessions, thereby optimizing the use of the body. This optimal utilization is always a very important consideration for anatomical departments, who in acknowledgment of the wish of the body donor strive for the maximum learning experience from each particular cadaver. In addition to dissecting the cadaver to learn the human anatomy, its employment could include the training of ultrasonography, invasive procedures such as thorax drainage, or the testing of new medical devices.

In an era in which the time spent on instructing anatomy in medical schools has been drastically reduced and the dissection of the human body by medical students has become scarce, certain anatomy departments focus more on postgraduate medical teaching. Especially for these training needs, an anatomical cadaver model providing tissue properties highly similar to real life patients, has become an important aspiration. Therefore, it would be of interest to investigate whether the F4L cadaver model is appropriate in this regard for airway management training.

Aim of the thesis

In this thesis, the main aim is to study the realism and suitability of the F4L cadaver model for postgraduate airway management training. The main research questions of this thesis are:

1. Is the F4L cadaver model a suitable and realistic model for the training and teaching of different airway management techniques?
2. How suitable and realistic is the F4L cadaver model for the training of the identification of the correct anatomical spot to incise for a 'surgical airway' (cricothyroidotomy), i.e., the identification of the cricothyroid membrane via palpation and ultrasonography?
3. What is the effectiveness of video-assisted fibreoptic intubation versus video-laryngoscopy in an established difficult airway F4L cadaver model?

Outline of the thesis

In the next chapters, the abovementioned research questions will be addressed. In the study described in **chapter 2**, the F4L cadaver, formalin-fixed cadaver model and synthetic model are compared for suitability and realism as a teaching model for different basic airway management techniques, namely facemask ventilation, tracheal intubation by direct laryngoscopy, and laryngeal mask insertion. In **chapter 3**, the study in which the F4L cadaver model was assessed for suitability and realism for advanced airway management maneuvers, i.e., videolaryngoscopy and fibreoptic intubation, is described. In **chapter 4**, the F4L cadaver model is studied for realism and suitability for the training in the identification of the cricothyroid membrane with palpation and with ultrasonography. **Chapter 5** describes the comparison of videolaryngoscopy with video-assisted fibreoptic intubation in a difficult F4L cadaver model. **Chapter 6** is the summary and general discussion of the work presented in the previous chapters and suggestions are made for further research. **Chapter 7** is the summary in Dutch (Nederlandse samenvatting).

Figure A. Facemask ventilation.

Figure B. Tracheal intubation by direct laryngoscopy.

Figure C. Tracheal intubation by videolaryngoscopy.

Figure D. Tracheal intubation with a flexible endoscope ('fibreoptic intubation')

Figure E. Insertion of the laryngeal mask

Figure F. Front-of-neck access: insertion of an endotracheal tube after cricothyroidotomy

Photos of figures A-E were kindly provided by dr. Lothar Schwarte and dr. Patrick Schober and of figure F was kindly provided by dr. Nico Hoogerwerf.

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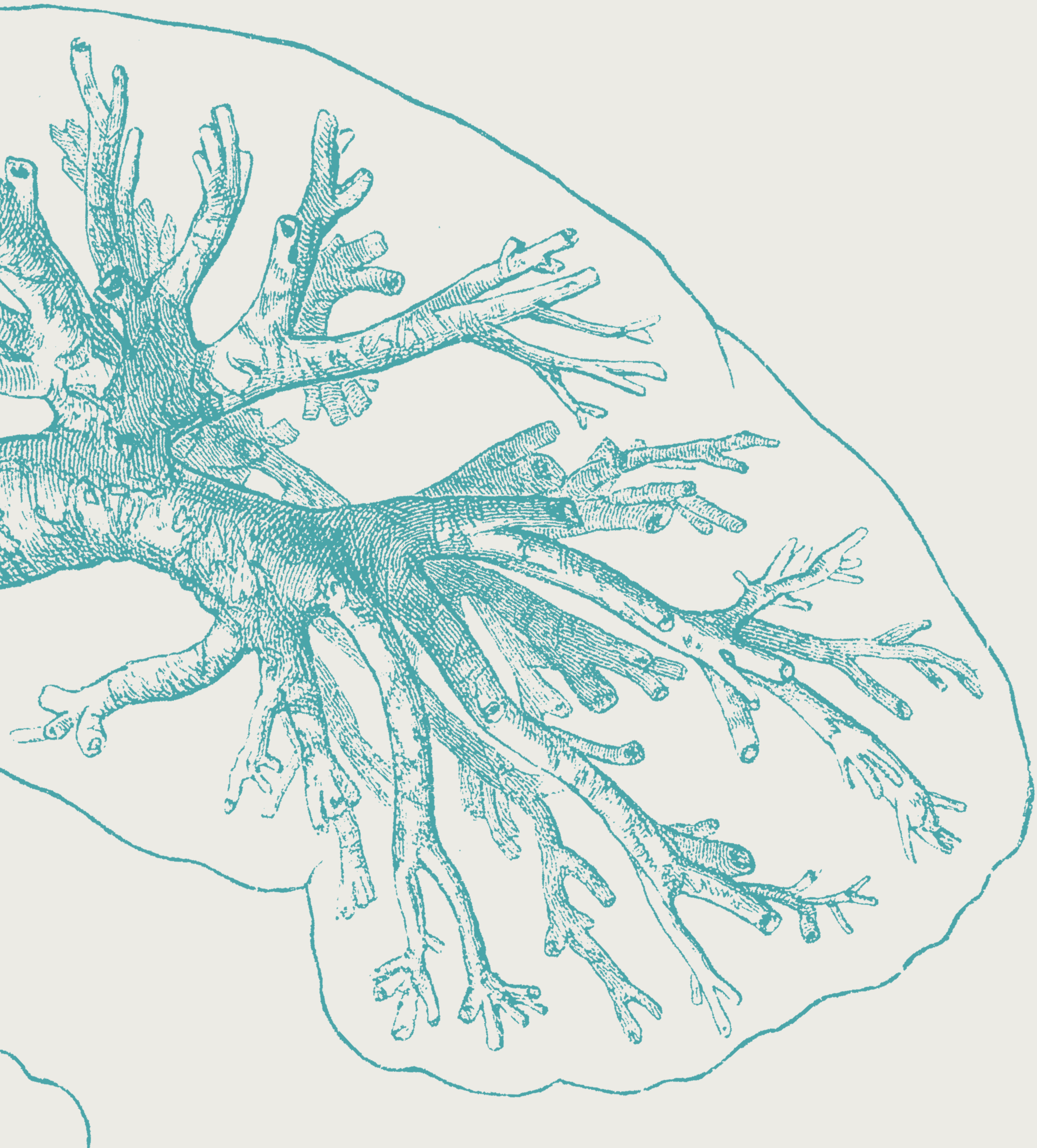

CHAPTER 2

Comparison of a novel cadaver model (fix for life) with the formalin-fixed cadaver and manikin model for suitability and realism in airway management training

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Patrick Schober
Lothar A. Schwarte

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Abstract

Background

Manikins are widely used in airway management training: however, simulation of realism and interpatient variability remains a challenge. We investigated whether cadavers embalmed with the novel Fix for Life (F4L) embalmment method are a suitable and realistic model for teaching 3 basic airway skills: facemask ventilation, tracheal intubation, and laryngeal mask insertion compared to a manikin (SimMan 3G) and formalin-fixed cadavers.

Methods

Thirty anesthesiologists and experienced residents ('operators') were instructed to perform the 3 airway techniques in 10 F4L, 10 formalin-fixed cadavers, and 1 manikin. The order of the model type was randomized per operator. Primary outcomes were the operators' ranking of each model type as a teaching model (total rank), ranking of the model types per technique, and an operator's average verbal rating score for suitability and realism of learning the technique on the model. Secondary outcomes were the percentages of successfully performed procedures per technique and per model (success rates in completing the respective airway maneuvers). For each of the airway techniques, the Friedman analysis of variance was used to compare the 3 models on mean operator ranking and mean verbal rating scores.

Results

Twenty-seven of 30 operators (90%) performed all airway techniques on all of the available models, whereas 3 operators performed the majority but not all of the airway maneuvers on all models for logistical reasons. The total number of attempts for each technique was 30 on the manikin, 292 in the F4L, and 282 on the formalin-fixed cadavers. The operators' median total ranking of each model type as a teaching model was 1 for F4L, 2 for the manikin and, 3 for the formalin-fixed cadavers ($P < 0.001$). F4L was considered the best model for mask ventilation ($P = 0.029$) and had a higher mean verbal rating score for realism in laryngeal mask airway insertion ($P = 0.043$). The F4L and manikin did not differ significantly in other scores for suitability and realism. The formalin-fixed cadaver was ranked last and received lowest scores in all procedures (all $P < 0.001$). Success rates of the procedures were highest in the manikin.

Conclusions

F4L cadavers were ranked highest for mask ventilation and were considered the most realistic model for training laryngeal mask insertion. Formalin-fixed cadavers are inappropriate for airway management training.

Key Points

- Question: Is a novel cadaver model a suitable and realistic model for acquiring airway management techniques?
- Findings: The novel cadaver model was ranked best for mask ventilation and was considered most realistic for laryngeal mask insertion.
- Meaning: The novel cadaver model could be a suited and more realistic alternative to manikins in training airway management techniques to novices.

Introduction

Airway management is a crucial component in anesthesiology, intensive care, and emergency medicine. Essential techniques to master for every airway managing practitioner include facemask ventilation, tracheal intubation, and laryngeal mask insertion.[1, 2] Historically, these skills were taught to novice practitioners on real patients undergoing anesthesia.[1] Commercially available manikins are also used to learn these techniques. However, manikins are made of synthetic material, and simulating the touch and feel and anatomical variation in real patients is difficult.[3] Fresh human cadavers can be used to train airway management techniques while providing the real look and tactile feel of patients.[4-8] However, practical and ethical considerations arise in the use of fresh human cadavers (e.g., limited timespan). Also, performing procedures on recently deceased patients without prior consent is not to be advocated.[9] The use of formalin-fixed cadavers of body donors has no time constraints, and such cadavers can be used for many years for the teaching of medical students and for scientific purposes. However, toxic levels of formaldehyde and tissue rigidity are a matter of concern.[10, 11] Recently, the embalmment method Fix for Life (F4L) has been developed, which allegedly preserves the haptic quality of fresh human material while only minimal amounts of formaldehyde are needed.[12] A wide scope of opportunities for teaching and learning airway management techniques as well as other procedures in a controlled setting could be possible with this embalmment method without the disadvantages of fresh material. The aim of our study was to determine whether the F4L cadavers are a suited and realistic airway management teaching model in comparison with an established simulation manikin and formalin-fixed cadavers.

Methods

The Medical Ethics Review Committee of VU University Medical Center, Amsterdam, The Netherlands (VUmc), judged the Medical Research Involving Human Subjects Act (WMO) not to be applicable, and official approval for the study was thus not required in accordance with Dutch law. This manuscript adheres to the applicable STROBE guidelines.[13] The feasibility of 3 different models to train several airway techniques (facemask ventilation, tracheal intubation, and laryngeal mask insertion) was studied. Given the anatomical heterogeneity of the human body compared to the homogeneity of the manikin, 10 F4L and 10 formalin-fixed cadavers were used and compared to 1 manikin to investigate whether the F4L-embalmed cadavers are a suited teaching model for novices to acquire airway management skills. Experienced airway management providers were asked to rate suitability and realism of the 3 models as detailed below.

Models

The cadavers were all donated to the Department of Anatomy and Neurosciences, VUmc. In accordance with Dutch law, all body donors had given written consent for body donation to science after death. The embalmment of the F4L and formalin-fixed cadavers was performed in the Department of Anatomy and Neurosciences, VUmc. The embalmment commenced within 24-72 hours after death. Infusion of the formalin embalmment fluid (a mixture of formaldehyde, alcohol, salicylic acid, various salts, thymol and water) and the F4L embalmment fluid (a patented mixture of aldehyde, other nonhazardous components and a small amount of formaldehyde) was via the femoral artery. Further embalmment procedures were done according to the prescribed method for a formaldehyde or F4L fixation. The manikin used was the SimMan 3G (Laerdal Medical, Stavanger, Norway), an established high-fidelity model for acquiring airway management skills and research in the simulation setting.[3, 14-16]

Experimental Protocol

Thirty physician anesthesiologists and senior residents in their third to fifth year of the 5-year residency training program were approached to perform the several airway techniques on the cadavers and manikin after obtaining informed consent. The inclusion criterion for participation was at least 100 successful tracheal intubations. Exclusion criteria were pregnancy or lactation of the operator because of teratogenicity of formaldehyde.[10, 11] Each operator was randomized by a sealed envelope technique for the order of the 3 model types in which the airway techniques were performed. The operator was instructed to complete all airway techniques on all the cadavers per model type before continuing to the next model type. All operators performed the techniques individually and were instructed not to discuss their experience with other operators. All the data were collected in the dissection room of the Department of Anatomy and Neurosciences, VUmc between December 2016 and February 2017.

All models were placed in the supine position, and positioning could be optimized (e.g., sniffing position) by the individual operator at his or her discretion using cushions. Any remaining oral fluids in the cadavers were suctioned. Each operator was asked to perform mask ventilation first, followed by tracheal intubation and finally insertion of a laryngeal mask airway (LM) per model. A successful procedure was defined as visible chest movements by ventilating with a self-inflating bag resuscitator (Manual Resuscitator Adult, Hsiner Co, Ltd Taichung City, Taiwan) within 30 seconds for mask ventilation and within 2 minutes for the other 2 techniques. Chest movements are difficult to detect in formalin-fixed cadavers due to tissue rigidity. These models were dissected, allowing direct assessment of airflow through the trachea. For mask ventilation, adult face masks sizes 4 and 5 (Air Cushion Mask with Valve, Hsiner Co, Ltd Taichung City, Taiwan) and Guedel airways sizes 5 and 6 (Mallinckrodt DAR S.r.l, Modena, Italy) were available at the operators' discretion. For the tracheal intubation, Macintosh laryngoscope blade sizes 3 and 4 (EmdaMed, Berkel en Roderijs, the Netherlands) as well as an intubating catheter (Frova, William Cook Europe ApS, Bjaeverskov, Denmark) could be used. Tracheal tubes were available in sizes 7.0 and 8.0 mm (Mallinckrodt Hi-Contour Oral/Nasal Tracheal Tube Cuffed, Covidien Ilc, Mansfield, MI). For LM airway insertion, the available laryngeal masks were sizes 4 and 5 (PROACT

Medical Ltd., Corby, UK). The use of water was allowed as a lubricant. During each airway management procedure, one assistant aided the operator on request (e.g., to hand equipment or to perform backward, upward, or rightward pressure [BURP] of the larynx),[17] and another documented the data on a standardized data form. Mask ventilations were objectively classified with the Han score, in which grade 1 defines ventilation by mask without aids, grade 2 describes ventilation by mask with oral airway (Guedel), grade 3 defines difficult mask ventilation requiring 2 practitioners, and grade 4 indicates inability to mask ventilate.[18] For tracheal intubation, the Cormack-Lehane grades were documented as reported by the operators.[19] After each airway management procedure, the operator was asked to give a verbal rating score (VRS) for suitability (defined as the operator's assessment of suitability of the model in teaching the novice the performed airway management skill) and for realism (defined as the operators assessment of look, feel and flexibility of the model compared to real patients) of the model, both on a scale of 1-10 (1 = worst score to 10 = best score).

Specifically for the F4L cadavers, the operators were additionally asked for VRSs for suitability and realism of the model in learning to manage the difficult airway. After completing all airway techniques on all of the different models the operators were instructed to consider all aspects of suitability and realism of the models in teaching the novice airway management skills and to rank the models accordingly. The operators were asked to rank the models first, second, and third separately for mask ventilation, tracheal intubation, and LM placement. Finally, the operators gave an overall total rank from 1 to 3 to the different models with respect to all aspects of suitability and realism in airway management skills, considering all the airway techniques together.

The primary outcome measures were the total ranking of the different models as airway teaching model, the ranking of the models per technique and the VRSs for suitability and realism of the models per technique. Secondary outcomes were success rates of the different techniques per model.

Statistical Analysis

IBM SPSS Statistics for Windows, Version 22.0. (IBM Corp, Armonk, NY) was used for statistical analysis. The Friedman analysis of variance (ANOVA) was used to test the null-hypothesis that ranking scores and VRSs are equally distributed among the F4L model, the formalin-fixed cadaver model, and the manikin model. When significant, pairwise comparisons were performed, and P values were corrected for multiple comparisons using the Dunn-Bonferroni test. Two-sided P values < 0.05 were considered significant.

While the Friedman ANOVA accounts for correlations between repeated measurements across the 3 model types, it does not account for within-participant correlation of repeated assessments of VRSs within each model type. Because we were interested in an overall VRS per technique per model rather than in individual scores for each cadaver, we reduced each individual's sequence of measurements within each model to a single number (ie, the mean of the score per technique and model). This "summary statistic approach," as recommended by Senn et al[20] and Matthews et al,[21] eliminated within-participant correlation within model, allowing a comparison of VRSs between the models with the Friedman ANOVA.

Sample Size

Sample size estimations were performed with STATA 13.0 (STATACorp, College Station, TX). We planned to use non-parametric tests for the analysis of ranks and ordinal rating scales, for which exact calculation of sample size is not possible. Therefore, we calculated the sample size for the parametric equivalent (here: repeated-measures ANOVA) and added 15% to this number as compensation.[22] We aimed to choose a sample size such that a 2-point score difference in verbal rating scale between any 2 models could be detected with 90% power on a 0.05 α level. Previous data on the correlation between repeated measurements of different participants in the 3 model types and estimates of the error variance were not available. We therefore performed sample size calculations using different correlations (0.1-0.9) as well as different error variances (0.5-5). The largest calculated sample size was 23 participants. Adding 15% for the non-parametric test, we would need 27 participants. To account for possible drop out of participants, we targeted 30 participants.

Results

In both the F4L and formalin-fixed cadaver group, there were 7 male and 3 female cadavers. Mean age of demise was similar: 79 years in the F4L group, and 80 years in the formalin-fixed group. Dental status was also similar in both groups; 5 F4L and 6 formalin-fixed cadavers had no teeth. The body habitus in both cadaver groups was also comparable, and cadavers with extremes in body composition (e.g., extreme obesity or cachexia) were not present in either group. Finally, mean thyromental distance was around 6.5 cm in both cadaver groups (6.3 cm in F4L, 6.7 cm in formalin) and 7.0 cm in the manikin.

Of the operators, 14 were females, and 16 were males. Mean age was 38.5 years (range 28-56 years). Twenty were anesthesiologists, and ten were senior residents, with a mean experience in airway management of 10.3 years (range 3-33 years). Twenty-seven of 30 operators (90%) performed all airway techniques on all of the available models (i.e., 21 mask ventilations, 21 LM airway insertions; and 21 intubations in 10 formalin-fixed cadavers, 10 F4L cadavers and 1 manikin), whereas 3 operators performed the majority but not all of the airway maneuvers for logistical reasons. However, all participants did perform all airway techniques in each of the model types. The total number of attempts for each technique was 30 on the manikin, 292 in the F4L and 282 on the formalin-fixed cadavers.

Ranking Outcomes

Median total ranking scores as airway training model for the F4L, manikin and formalin-fixed cadaver models were 1, 2, and 3, respectively ($P < 0.001$). In the ranking of mask ventilation, F4L was ranked significantly higher compared to the manikin and formalin-fixed cadaver. For intubation and LM airway insertion, both F4L and manikin ranked higher than the formalin-fixed cadaver. The other ranking outcomes for mask ventilation, tracheal intubation and LM airway insertion are summarized in Table 1.

Verbal Rating Scores

The mean VRSs regarding suitability and realism of the different models in teaching skills to novice providers for the different airway management techniques are presented in Table 2. The mean VRSs were overall significantly different ($P < 0.001$).

Pairwise comparisons showed that F4L had a significantly higher VRS for realism in LM airway insertion compared to the manikin (P = 0.043). All the VRSs of the F4L or manikin compared to the formalin-fixed cadavers were significantly higher (P < 0.001). The mean VRSs for suitability and realism of the F4L cadaver as a difficult airway teaching model were 7.7 of 10 (95% CI, 7.2-8.2) and 7.0 of 10 (95% CI, 6.4-7.6), respectively.

Success Rates

In mask ventilation, 100% of attempts were successful on the manikin, 95.9% in F4L, and 96.8% in formalin-fixed cadavers. The success rates in intubation were 100% in manikins, 61% in F4L, and 0% in formalin-fixed cadavers. For LM airway insertion, 73.3% of attempts in the manikin, 69.5% in F4L, and 2.8% in formalin-fixed cadavers were successful. Han scores and Cormack-Lehane grades, application of BURP, and use of an intubating catheter in the different models are presented in the Figure.

Table 1. Summary of ranking outcomes.

Outcome	Median Rank (Range)			Pairwise Comparisons (*P* values)		
	F4L (n = 30)	Manikin (n = 30)	Formalin (n = 30)	F4L versus Manikin	F4L versus Formalin	Manikin versus Formalin
Total ranking	1 (1-1)	2 (1-2)	3 (3-3)	> 0.99	< 0.001	< 0.001
Mask ventilation	1 (1-2)	2 (1-3)	3 (2-3)	0.029	< 0.001	< 0.001
Intubation	2 (1-2)	1 (1-2)	3 (3-3)	0.21	< 0.001	< 0.001
LM airway insertion	1 (1-2)	2 (1-2)	3 (3-3)	0.91	< 0.001	< 0.001

Median for total ranking of the models and median rank per technique (range in brackets). Ranking: 1=best, 3=worst. P values are given for pairwise comparisons performed after significant Friedman analysis of variance. A P value < 0.05 after correcting for multiple comparisons was considered a significant difference in ranking.
Abbreviations: F4L, Fix for Life; LM, laryngeal mask.

Table 2. Mean Verbal Rating Scores.

Technique			Mean Score (95% CI)
Mask Ventilation	*Suitability*	Manikin	7.4 (7.0-7.8)
		F4L	7.2 (6.6-7.7)
		Formalin	3.4 (2.7-4.1)*
	Realism	Manikin	5.9 (5.3-6.6)
		F4L	7.0 (6.5-7.5)
		Formalin	2.8 (2.2-3.4)*
Intubation	*Suitability*	Manikin	7.2 (6.7-7.7)
		F4L	5.4 (4.8-6.0)
		Formalin	1.3 (1.1-1.4)*
	Realism	Manikin	5.9 (5.3-6.6)
		F4L	5.7 (5.1-6.2)
		Formalin	1.6 (1.2-2.0)*
LM airway insertion	*Suitability*	Manikin	4.2 (3.4-5.0)
		F4L	5.0 (4.5-5.5)
		Formalin	1.2 (1.1-1.3)*
	Realism	Manikin	3.6 (2.8-4.5)
		F4L	5.0 (4.4-5.6)Δ

Mean scores with 95% CI for suitability and realism per model in teaching the different techniques. For the F4L and formalin-fixed cadaver models, the data being summarized are the mean scores across the multiple observations per operator, while a single score per operator was obtained for the manikin. A P value < 0.05 after correcting for multiple comparisons was considered a significant difference in score.
Abbreviations: F4L, Fix for Life; LM, laryngeal mask.
** = significant pairwise comparison (P < 0.001) versus all other models.*
Δ = significant pairwise comparison (P = 0.043) versus the manikin

2

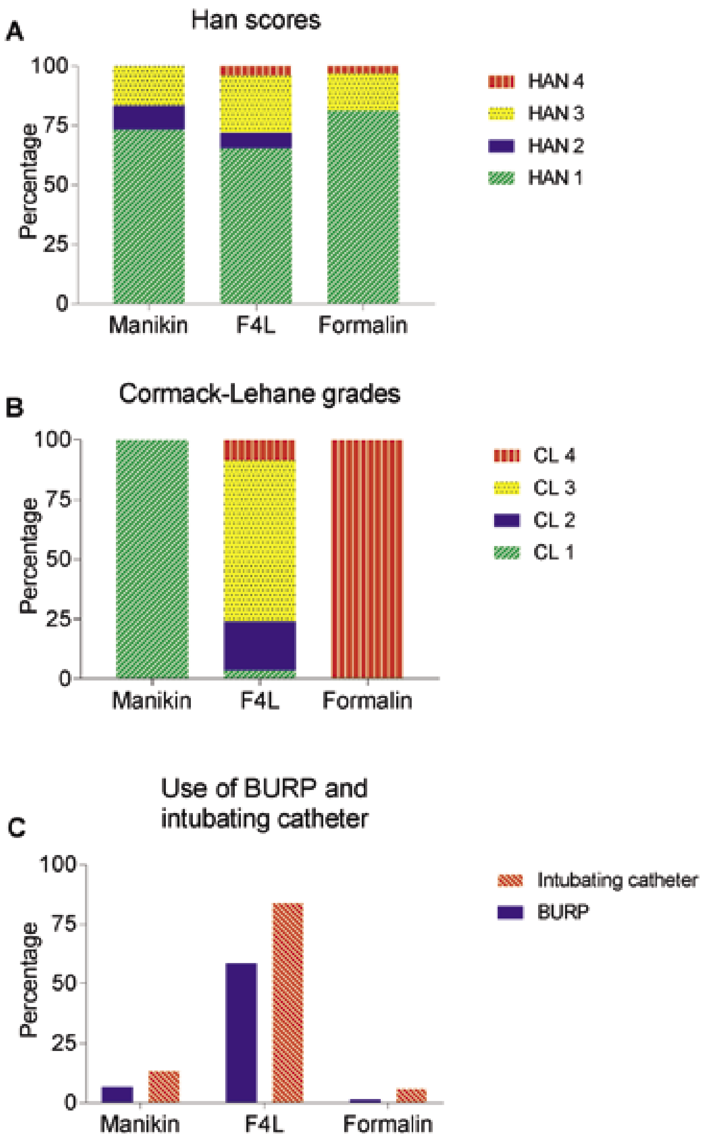

Figure.
Percentages of Han scores (A), Cormack-Lehane grades (B), use of backward upward rightward pressure (BURP) and intubating catheter (C) in the different models. Low percentages of BURP and use of an intubating catheter in formalin-fixed cadavers resulting from operators not attempting laryngoscopy because of the rigidity of the jaw. F4L indicates Fix for Life.

Discussion

This is the first study to use F4L-embalmed cadavers as an airway management training model. We investigated the suitability and realism of this cadaver model compared to an established airway training manikin and standard formalin-fixed cadavers to teach essential airway management skills. Our study demonstrates that the F4L cadaver scores better than the manikin in some aspects of teaching these procedures, while it is as good as the manikin regarding other aspects. More specifically, in the overall score for mask ventilation, the F4L cadaver was ranked significantly higher than the manikin. Moreover, the F4L cadaver was considered a more realistic model for the insertion of an LM airway. In addition, the F4L cadaver received promising VRSs regarding suitability and realism for teaching difficult airway management.

Although simulation training has found a permanent place in daily anesthesiology practice and training programmes and trainees seem to benefit from it (e.g., in training complex team scenarios), there is an ongoing discussion about the validity and reliability of airway skill simulators.[3, 23, 24] As an alternative to manikin simulators, cadavers can be used to train airway management techniques. Fresh frozen cadaver models have been found useful to train airway management techniques.[25] However, the logistics required for defrosting and the limited timespan in which the material is available for use because of decomposition limits the usefulness as teaching model. Only 1 previous study assessed embalmed cadavers as an airway management training model. The study by Szűcs et al[7] used the Thiel embalmment method for cadavers, which has also been used and studied in other contexts such as surgical procedures.[26-29] Similar to our data, these authors found higher mean VRSs for mask ventilation for the cadaver model compared to manikins. However, while Thiel-embalmed cadavers need to be stored for several months for optimal embalmment, F4L-embalmed cadavers are immediately available for use and can be used for a minimum of 2 years (presumably much longer, but long-term experience is not yet available because the technique is relatively new). Our findings suggest that the F4L embalmment method can be a useful alternative to the Thiel method to train airway management techniques in anatomical institutions.

This present study is the first to show that formalin-fixed cadavers do not seem suited for the acquisition of airway management skills, as shown by the low ranking and verbal rating scales. A likely explanation is the rigidity of the cadaver resulting from embalming with formaldehyde.[27, 28] One recent study analyzed the biomechanical properties of human spines embalmed with F4L and found an increase in spinal tissue stiffness.[30] This finding might explain our results of a relatively high percentage of Cormack-Lehane grades 3 and 4, application of BURP, and insertion of an intubating catheter in the F4L cadaver. These results might also explain the high VRSs given in the assessment of suitability and realism (7.7 and 7.0, respectively) of the F4L cadaver as a model for difficult airway procedures. Possible future adjustments to the F4L mixture in relation to the amount of formaldehyde used could lead to even more flexibility of the joints of the F4L cadaver.

There are limitations to our study. First, it was not possible to blind the participants with respect to the model type.
Second, there is no universally accepted or validated method to measure suitability or realism of an airway model. Because we needed to rely on subjective assessments, we deliberately recruited participants with extensive experience. Literature suggests that approximately 50 tracheal intubations are required to achieve a plateau phase in this skill.[31, 32] We chose to double this number and defined 100 successful tracheal intubations as the minimum requirement. This ensured that all participants were well experienced, such that they all had a common framework to which they could compare the realism and suitability of the models. The participants' assessment of suitability and realism was measured using a verbal rating scale. In a previous study by Szűcs et al,[7] a similar verbal rating scale was used and demonstrated that this scale is useful to reveal differences between airway models. Moreover, similar scales are abundantly used in other fields of science for quantification of subjective assessments, and these scores are well validated for this purpose. Examples include the subjective assessment of pain and numerous scales in psychology.[33]
Third, we only used one type of manikin, while there are various manikins available on the market, and our results may not be applicable to other manikins. However, we selected a well-established and widely used manikin particularly for airway management.[3, 14-16] Our observed success rates of intubation and LM airway insertion are comparable to those reported for the SimMan by Schebesta et al[3] (97.5% and

67.5%, respectively). We only used 1 manikin compared to 10 F4L and 10 formalin-fixed cadavers. This is because manikins of one type are virtually identical, while human bodies differ in anatomy from individual to individual, which approaches daily practice more closely. Older age, presence of a beard and lack of teeth are associated with a more difficult mask ventilation.[34-36] The cadavers studied had a mean age of 80 years, and some lacked dentition. This could explain why in the F4L cadavers, Han scores 3 (requiring 2 practitioners) and 4 (impossible mask ventilation) were reported more often than in manikins.

Fourth, we provided a limited range of airway instruments the operators could use. However, the adult facemask, a standard Macintosh laryngoscope blade, and an LM airway are the basic airway instruments, and a novice airway practitioner should be acquainted with these early in his or her career.[1] More advanced airway instruments and techniques such as the videolaryngoscope or fibreoptic intubation should be studied in the F4L cadaver in the future.

In conclusion, we found that the F4L cadaver model was judged by specialists to be the most appropriate model for teaching of mask ventilation, as well as the most realistic model for LM airway insertion. We see the potential for the F4L cadaver in skills training to manage the more difficult airway and possibly other acute medical procedures. The formalin-fixed cadavers are inappropriate for airway management training.

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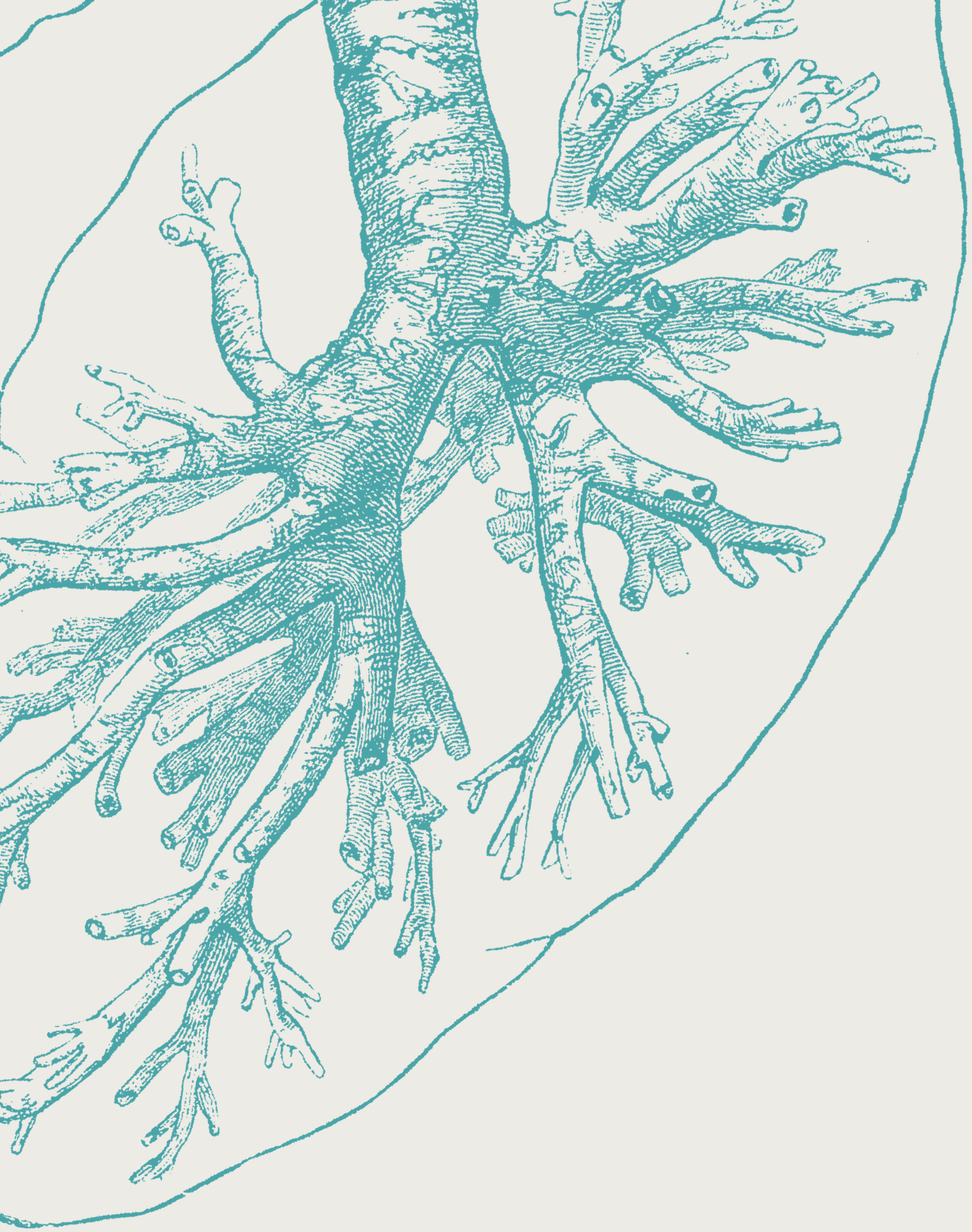

CHAPTER 3

Suitability and realism of the novel Fix for Life cadaver model for videolaryngoscopy and fibreoptic tracheoscopy in airway management training

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Abstract

Background

Videolaryngoscopy is increasingly advocated as the standard intubation technique, while fibreoptic intubation is broadly regarded as the 'gold standard' for difficult airways. Traditionally, the training of these techniques is on patients, though manikins, simulators and cadavers are also used, with their respective limitations. In this study, we investigated whether the novel 'Fix for Life' (F4L) cadaver model is a suitable and realistic model for the teaching of these two intubation techniques to novices in airway management.

Methods

Forty consultant anaesthetists and senior trainees were instructed to perform tracheal intubation with videolaryngoscopy and fibreoptic tracheoscopy in four F4L cadaver models. The primary outcome measure was the verbal rating scores (scale 1-10, higher scores indicate a better rating) for suitability and for realism of the F4L cadavers as training model for these techniques. Secondary outcomes included success rates of the procedures and the time to successful completion of the procedures.

Results

The mean verbal rating scores for suitability and realism for videolaryngoscopy was 8.3 (95% CI, 7.9-8.6) and 7.2 (95% CI, 6.7-7.6), respectively. For fibreoptic tracheoscopy, suitability was 8.2 (95% CI, 7.9-8.5) and realism 7.5 (95% CI, 7.1-7.8). In videolaryngoscopy, 100% of the procedures were successful. The mean (SD) time until successful tracheal intubation was 34.8 (30.9) s. For fibreoptic tracheoscopy, the success rate was 96.3%, with a mean time of 89.4 (80.1) s.

Conclusions

We conclude that the F4L cadaver model is a suitable and realistic model to train and teach tracheal intubation with videolaryngoscopy and fibreoptic tracheoscopy to novices in airway management training.

Background

Videolaryngoscopy (VLS) is an established standard airway technique, while the use of flexible fibreoptic or video tracheoscopy (FOT) is broadly regarded as the 'gold standard' when confronted with a difficult airway.[1-3] Traditionally, novice airway practitioners learn these techniques on patients in the operating room, though synthetic manikins or simulators are also being used, with their respective limitations.[4] The advantage of training outside the operating room is an environment free of risks to patients, and the option of constructing clinical scenarios not regularly encountered in practice.[5] However, mimicking the characteristics of human anatomy in synthetic manikins and simulators is difficult.[6] Human cadavers of persons who donated their body to science after death are potentially of added value in the training of VLS and FOT.[7-9] Such cadaver models reflect the variance in anatomy also encountered in real patients. However, the method of conservation of these cadaver models is crucial, because the traditional embalmment with large amounts of formaldehyde causes the tissues to be rigid and makes airway management training rather unrealistic. Recently, a new cadaver model has been described, embalmed with 'Fix for Life' (F4L), which trainee and specialist airway practitioners have found to be realistic and suited for teaching basic airway management techniques, e.g., mask ventilation.[10] In the present study, we investigated the suitability and realism of the F4L cadaver model for the training of two advanced video airway techniques, i.e., VLS and FOT for tracheal intubation.

Methods

The study was approved by the biobank and ethics committee of the Amsterdam UMC, Vrije Universiteit, Amsterdam, the Netherlands. All data were collected in the anatomy laboratory of the department of Anatomy and Neurosciences.

Participants

Forty consultant anaesthetists and senior trainees (4th and 5th year of the 5-year training program) were recruited to participate in the study. Inclusion criteria were familiarity with VLS and FOT for tracheal intubation, i.e., the participants are familiar with and have received training in these techniques. Due to formaldehyde being used at the anatomical facility, exclusion criteria were pregnancy and lactation. Before participating, all consultants and trainees gave written informed consent. Age, sex, number of years of professional experience and an estimation of the number of tracheal intubations with VLS and FOT (including anaesthetised and awake procedures) of the participants were recorded.

F4L cadaver models

The four F4L cadavers used in this study were from body donors who donated their body to science after death through written consent, in accordance with Dutch legislation. Embalmment was performed within 24-72 hours after demise. The cadavers were embalmed with the F4L embalmment fluids, according to the embalmment protocol for F4L fixation.[11] Basic characteristics of the cadavers (age at demise, sex, length, weight, body mass index) and morphometric predictors of difficult intubation (dental status, neck circumference, thyromental and sternomental distance) were recorded. The Cormack-Lehane grade of each F4L cadaver model was assessed in agreement by 2 senior consultant anaesthetists via direct laryngoscopy (Macintosh blade size 3) before the start of the study.

Study protocol

Each participant performed the VLS and FOT procedures individually, with no other participants present in the room at the same time. The participants were instructed to first intubate the tracheas of the F4L cadaver models with the VLS (GlideScope®, Verathon Medical, Burnaby, Canada) with a size 3 blade. After completion of the VLS procedures on all cadaver models, the participants performed tracheal intubation via FOT (Ambu® aScope™ 4, Ambu A/S, Ballerup, Denmark, regular size, outer diameter 5.5 mm) on all four F4L cadaver models. Tracheal tubes were available in different sizes from 6.0 mm to 8.0 mm (Covidien™, Mansfield, MA). The procedures using VLS and FOT were performed in the same order for all participants on all four F4L cadavers. The participants were allowed to optimize the position of the head of the cadaver according to their own preferences (e.g., sniffing position or ramping). Any fluids present in the oropharyngeal cavity of the cadavers were suctioned before starting the procedures. One of the researchers present served as a 'non-obstructive' assistant to the participant to provide instruments (e.g., tracheal tube), or to apply jaw thrust or backward, upward, or rightward pressure (BURP) of the larynx, or other optimizing manoeuvres, if requested. For the FOT procedure, the participants were instructed to perform a nasotracheal intubation. The tracheal tube was allowed to be pre-fixed ('loaded') on the tracheoscope or pre-inserted through the nose of the cadaver model prior to the start of the FOT procedure, according to the preference of the participant. Lubricant was applied to the FOT device and tracheal tube, as required. Also, the participants were allowed to take their preferred position relative to the cadaver model (e.g., standing behind the 'patient' or next to the 'patient').

The time of the procedure (in seconds, [s]) was recorded for each intubation attempt. For the VLS intubation procedure, recording of time started when the tip of the VLS entered the mouth of the cadaver model and stopped when the tracheal tube was cuffed. Time of the FOT procedure was measured when the tip of the tracheoscope entered the cadaver's nose (or the pre-inserted tracheal tube) and also stopped when the tracheal tube was cuffed. Active assistance upon request of the participant (e.g., jaw thrust) was recorded. Success of the VLS or FOT procedure was defined as a correct intubation of the trachea. In the VLS, correct placement of the tracheal tube was ascertained by direct view of the passing of the tube through the vocal cords on the GlideScope videoscreen by 2 of the present researchers. For the FOT procedures, correct placement of the tracheal tube was ascertained by confirming view of the carina on the aScope videoscreen. Failure of the procedures were additionally recorded if the participant resigned the task or if the time of the VLS procedure exceeded 5 minutes, or 10 minutes for the FOT procedure.

After completion of the intubation procedures on all cadaver models with VLS, and subsequently with FOT, the participants were asked to give an overall verbal rating score (VRS) for each technique.[7, 10, 12] The participants were asked to rate the F4L cadaver model for suitability as a training model to learn VLS or FOT ("Considering real-life patients as a reference, how suitable is the F4L cadaver model as a teaching model to teach novices the use of VLS or FOT with regard to the technical aspects?"). Thereafter, they were asked to score the model on realism ("Considering real-life patients as a reference, how realistic is the F4L cadaver model as a teaching model to teach novices the use of VLS or FOT with regard to look, feel and flexibility?"). The VRSs were given on a scale of 1 to 10 (1 = worst score, 10 = best score). Any relevant narrative feedback was also recorded.

Outcome measures and statistical analysis

The primary outcome measures were the VRSs for suitability and for realism of the F4L cadaver as training model for VLS and FOT respectively. Secondary outcomes were success rates of the procedures, the time to successful intubation of the trachea and whether assistance was needed.

For this study we used a convenience sample of 40 consultant anaesthetists and senior trainees, and four F4L cadavers per participant. Statistical analysis was performed using SPSS, version 26 (IBM Corp, Armonk, NY). The mean VRSs are presented with calculated 95% confidence intervals (95% CI). Success rates of the VLS and FOT procedures are presented as proportions. Time, given in seconds, until successful intubation of the trachea is presented in mean with standard deviation (SD). The Mann-Whitney U test was used to compare the VRSs given by consultant anaesthetists and the senior trainees. A P value < 0.05 was considered significant.

Results

The participants included 26 consultant anaesthetists and 14 senior trainees with a mean (SD) professional experience of 11.7 (8.0) years. The male/female ratio was 20/20. Mean (SD) age was 40.2 (9.4) years. Self-estimated previous experience with VLS assisted tracheal intubations was < 20 in 5% of participants, and ≥ 20 in 95% of participants. Experience with FOT on patients was < 20 in 47.5% of participants, and ≥ 20 in 52.5% of participants. The characteristics of the 4 F4L cadaver models are presented in table 1. All 40 participants completed all of the procedures on the 4 F4L cadaver models for a total of 160 VLS and 160 FOT assisted tracheal intubation attempts.

For suitability of training VLS, the mean VRS was 8.3 (95% CI, 7.9-8.6). For realism, the mean VRS was 7.2 (95% CI, 6.7-7.6). The suitability of the F4L cadaver model for FOT was rated with a mean VRS of 8.2 (95% CI, 7.9-8.5) and for realism, the mean VRS was 7.5 (95% CI, 7.1-7.8).

The results in proportion of successful procedures, time until successful completion and proportion of assistance needed are presented in table 2.

No significant differences were observed in the mean (SD) VRSs given by consultant anaesthetists versus trainees respectively for suitability for VLS (8.5 [1.1] versus 7.9 [1.1], P = 0.190), realism for VLS (7.2 [1.4] versus 7.1 [1.5], P = 0.604), suitability for FOT (8.2 [1.0] versus 8.2 [0.8], P = 0.747), and realism for FOT (7.3 [1.1] versus 7.6 [1.0], P = 0.332). Additional comparative analyses of mean (SD) VRSs given by participants with < 20 and ≥ 20 FOT performed in patients respectively, revealed no significant differences in suitability for FOT (8.2 [1.1] versus 8.3 [0.8], P = 0.979) or for realism for FOT (7.7 [1.1] versus 7.2 [1.0], P = 0.161). For the mean (SD) VRSs given by participants with < 20 and ≥ 20 VLS performed in patients respectively, also no significant differences were observed in suitability for VLS (8.5 [0.7] versus 8.3 [1.2], P = 0.785), and realism for VLS (6.5 [0.7] versus 7.2 [1.4], P = 0.369).

The additional, narrative feedback provided by the participants was that the F4L cadaver model was 'more rigid', had a 'paler or different colour', and was 'dryer' in regard to real patients. Other remarks were the 'setting differences' (e.g., no beeping sounds of monitors), and the 'not awake patient'.

A typical example of the laryngeal view with VLS is presented in figure 1.

Table 1. Characteristics of the 4 Fix for Life (F4L) cadaver models.

	Cadaver 1	Cadaver 2	Cadaver 3	Cadaver 4
Age at demise (y)	89	70	68	90
Sex	Male	Male	Female	Female
Weight (kg)	75	54	52	66
Length (m)	1.75	1.73	1.70	1.67
Body mass index (kg.m^{-2})	24.5	18	18	23.7
Neck circumference (cm)	47	38	42	52
Thyromental distance (cm)	6.5	7.5	6	5.5
Sternomental distance (cm)	13.5	15	14	13.5
Dental status	Toothless	Toothless	Incomplete	Toothless
Cormack-Lehane grade	4	2	2	3

Table 2. Results in Verbal Rating Scores (VRS) for suitability and for realism, success rates, time until successful completion, and requested assistance of the videolaryngoscopy (VLS) and flexible tracheoscopy (FOT) in the F4L cadaver model.

	VLS	FOT
VRS suitability	8.3 (7.9-8.6)	8.2 (7.9-8.5)
VRS realism	7.2 (6.7-7.6)	7.5 (7.1-7.8)
Success rate	160 (100%)	154 (96.3%)
Time until completion; s	34.8 (30.9)	89.4 (80.1)
Assistance needed	22 (13.8%)	126 (78.8%)

Values are mean (95% confidence interval or standard deviation) or number (proportion).

Figure 1.
Laryngeal view with the videolaryngoscope. (Photo by Lothar Schwarte).

Discussion

This is the first study to investigate the suitability and the realism of the novel F4L cadaver model as airway management training model for both VLS and FOT. Our results suggest that experienced airway practitioners regard the F4L cadaver as a suitable and realistic training model for both VLS and FOT procedures.

Different models for VLS and FOT training have been described, ranging from manikins, simulators,[13-15] animals[16] and cadaver models.[7, 9, 17] Learning these airway techniques on different types of models outside the operating room could be effective, and time efficient.[4, 5, 18] In our study, the participants rated the F4L cadaver model high with regard to suitability and realism, considering real patients as a reference. This finding is comparable to an earlier study in which the F4L cadaver model was found to be a realistic and suitable model for more basic airway manoeuvres.[10] For example, suitability and realism as a teaching model for mask ventilation were scored as 7.2 and 7.0 respectively, which is consistent with our current findings. These scores are promising, and support the use of the F4L cadaver model for airway management training programmes. The results of the present study suggest extending the application spectrum of F4L cadavers from these more basic airway manoeuvres to the advanced airway manoeuvres, i.e., VLS and FOT. The F4L cadaver could be a useful asset to reduce the learning period of VLS and FOT procedures outside the operating theatre.

Simulation training has found a place in anaesthesia training programmes, although there is discussion about the degree of reality a simulation model should have.[6, 19, 20] Using the F4L cadaver in addition to simulators and manikins in airway management training could provide for optimal preparation of novice airway practitioners before executing these techniques on actual patients. In addition, experienced airway practitioners can refresh or optimize their technical skills outside the operating room. In the ever faster evolving market of novel airway devices, the F4L cadaver model may provide a safe 'test field' to test and train new devices before their first application in a real patient.

The success rate of intubation with VLS was 100%, which is within the range of reported success rates of 73-100% in a recent meta-analysis of Glidescope VLS.[21] Also, the mean time to successfully complete the VLS procedure did not exceed those previously reported.[21, 22] For the FOT procedures, the success rate was 96.3%, which is comparable with reported success rates from an analysis of 1612 fibreoptic intubation cases.[23] In this study, 93.9% of FOT procedures were successfully completed within 3 minutes. In our study on the F4L cadaver models, this was 90.9% within the same timeframe. In a recent manikin study, the success rate for nasotracheal intubation of the trachea with the Ambu aScope 3 was 95%.[24] In this report, the mean (SD) time for proper tracheal tube placement was 70 (33) seconds, which is on average 20 seconds faster compared to our measured mean time of approximately 90 seconds. However, only a single manikin was used in that study. In our study, occasionally oropharyngeal fluid collections were encountered during the procedure and were suctioned with the Ambu aScope, which adds time to the duration of the procedure. However, the F4L cadaver model probably resembles the clinical setting more closely, where blood or secretions may be encountered in the airway of patients.

There are some limitations to our study. The F4L cadaver model was not compared with other cadaveric preparations or manikins with regard to the performance of VLS and FOT, thus no conclusions can be drawn on its performance in comparison to these other models. We used only one type of VLS (Glidescope) and FOT (Ambu aScope 3) device, while there are multiple types available in practice. Our results are therefore not necessarily generalizable to other device types, but we did use broadly distributed devices, also mostly used in our hospital. We are aware that not every hospital has the availability of a cadaver lab, but a university hospital as ours serves also as a regional training centre, and airway courses are given to an (inter-)national public where the cadaver lab can be integrated in the curriculum. However, currently used standard formaldehyde-based fixation techniques result in very rigid cadavers, which are not useful for airway management training.[10, 25] While fresh frozen cadavers have the advantage that they are realistic after thawing, and are used in airway management training,[26] continuing decomposition remains a major limitation. Ideally, a preservation technique would avert decomposition while at the same time preserve the natural characteristics of human tissue.

The F4L preservation method appears to come quite close to this ideal as it provides for a flexible human cadaver model with comparable tissue quality as fresh frozen cadavers, yet without the disadvantage of ongoing decomposition. In contrast to the use of formaldehyde preserved cadaveric preparations, the necessary amount of formaldehyde in F4L cadaver models is much smaller, which reduces toxicity. A main advantage of formaldehyde preserved cadaveric preparation is the long duration these specimens can be used, usually for multiple years. In our experience, a well preserved F4L cadaver model can generally be used for a minimum of two years before the tissue quality diminishes. Due to these properties, the F4L cadaver is utilised at our facilities for the training and teaching of surgical procedures, and also for ultrasonography airway management courses in identifying anatomical structures in patients (e.g. the cricothyroid membrane for front-of-neck access).[27] Regarding our field of interest, the F4L cadaver model can also be used to learn to handle different airway devices, while providing a rather realistic anatomical view. For this first study of VLS and FOT in F4L cadaver models, we selected cadavers with rather normal habitus and morphology. For follow-up studies and our airway training courses, cadavers with more challenging characteristics (e.g., obesity) can also be selected and preserved.

Conclusions

In conclusion, our results suggest that the F4L cadaver model is a realistic and suitable model for the training and teaching of VLS and FOT airway manoeuvres to novices in airway management. We see potential for the F4L cadaver model to be incorporated in airway training curricula.

List of abbreviations

CI: Confidence Interval
F4L: Fix for Life
FOT: Fibreoptic tracheoscopy
SD: Standard Deviation
VLS: Videolaryngoscopy
VRS: Verbal Rating Scale

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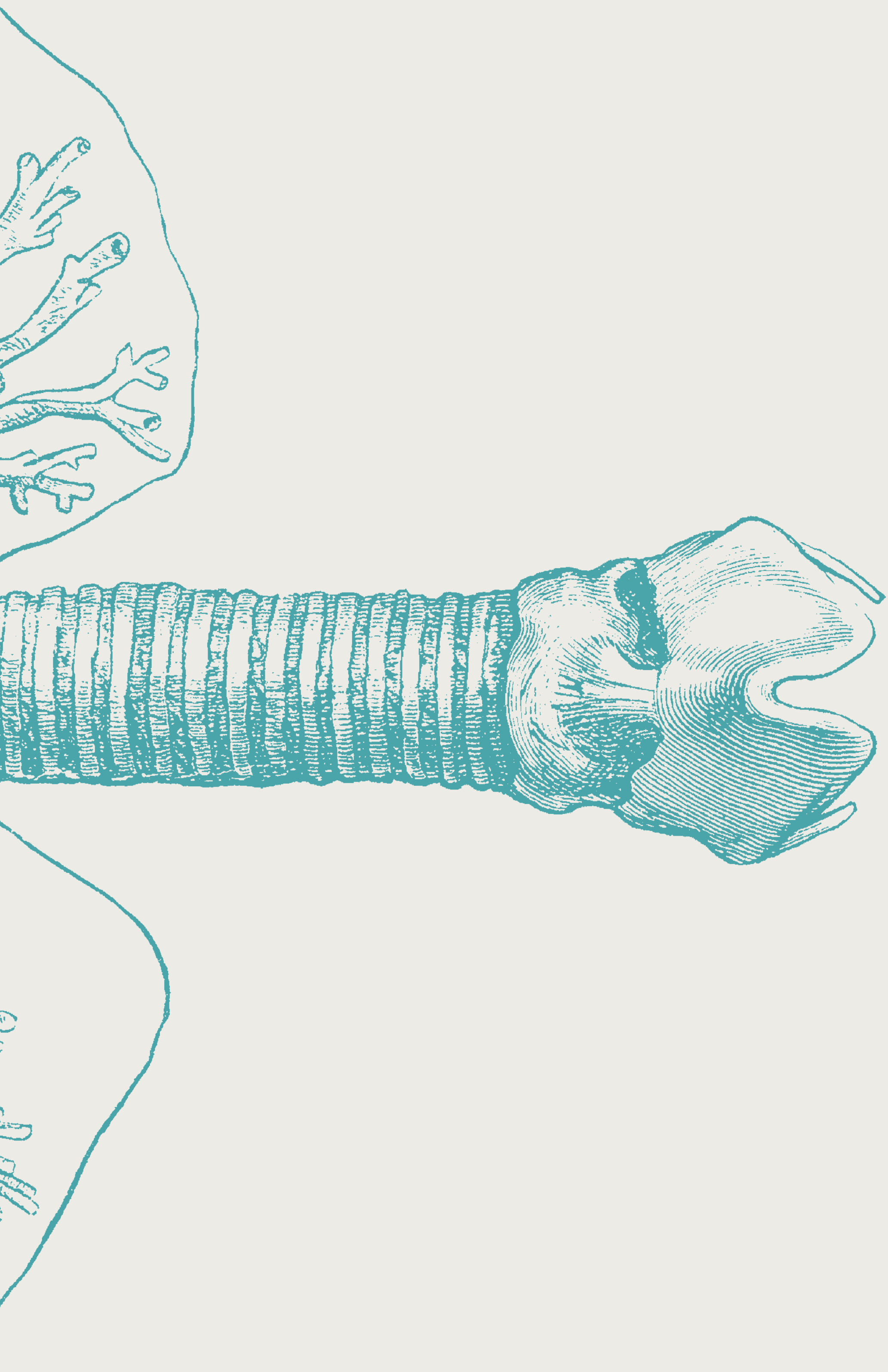

CHAPTER 4

Cricothyroid membrane identification with ultrasonography and palpation in cadavers with a novel fixation technique (Fix for Life): a laboratory investigation

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Abstract

Background

Front-of-neck access is a rare but potentially life-saving procedure. The crucial first step is the localisation of the cricothyroid membrane, but palpation is markedly unreliable. Ultrasonography seems superior to palpation, but evidence is conflicting. Whatever technique is used, training in front-of-neck access is essential. Training models range from manikins to formalin-fixated cadaver and animal models, all with inherent limitations. Recently, the Fix for Live (F4L) cadaver model has been developed. We investigated (i) whether F4L is suitable to train the identification of the cricothyroid membrane, and (ii) whether ultrasonography is superior to palpation.

Methods

Forty anesthesiology practitioners were randomised to identify the cricothyroid membrane in 3 female F4L cadaver models via palpation or ultrasonography. The primary outcomes were verbal rating scores on 1-10 scales to determine realism and suitability of the F4L cadaver as teaching model in locating the cricothyroid membrane by palpation or ultrasonography. Secondary outcomes were the success rates and time required to identify the cricothyroid membrane.

Results

The median (95% CI) verbal rating score for realism was 8 (7-8) in the palpation group and 8 (8-9) in the ultrasonography group. For suitability, the verbal rating scores were 8 (8-8) in the palpation group and 8.5 (8-10) in the ultrasonography group. Success rate was 70.0% in the palpation group, and 91.7% in the ultrasonography group ($P = 0.011$). Time to identify the cricothyroid membrane was longer with ultrasonography ($P < 0.001$).

Conclusions

We conclude that F4L cadavers are realistic and suitable to train the identification of the cricothyroid membrane. Our findings also confirm the superiority of ultrasonography versus palpation in successfully locating the cricothyroid membrane.

Introduction

Emergency front-of-neck access to the airway by performing a cricothyroidotomy is the last resort in a 'can't intubate can't oxygenate' situation.[1] The crucial initial step in this procedure is the correct identification of the cricothyroid membrane (CTM). Herein, the traditional palpation method has proven challenging in multiple studies.[2-4] Particularly in female patients, the reported success rates to correctly identify the CTM are low, ranging from 0-71%.[5-9] The use of ultrasonography in locating the CTM is promising and may increase the success rate,[10-13] but evidence is yet conflicting.[14] Using ultrasonography preprocedurally in elective anesthesia cases has been propagated as a standard operational procedure to identify and mark the CTM when inspection or palpation of landmarks is difficult.[15-18]
The training of cricothyroidotomy in the clinical setting is difficult since the incidence is low, and the acute setting is not appropriate to train this procedure.[19, 20] Manikins and animals serve as training models, but they do not closely reflect human anatomy nor its variance.[21] Embalmed or fresh human cadavers have also been used. However, using recently deceased patients is not always ethical and fresh frozen human cadavers of body donors to science have time constraints, due to ongoing putrefaction.[22] Formalin-fixed cadavers become very firm and inflexible. Recently, Fix for Life (F4L) embalmed cadavers have been described to be suitable and realistic in the training of basic airway management techniques (e.g., mask ventilation), without the aforementioned disadvantages.[23] The F4L cadaver model could also be appropriate to train in identification of the CTM, but additionally offer the possibility to actually perform the cricothyroidotomy in an educational setting. In the current study, the primary aim was to determine if anesthesiology participants would judge the F4L cadaver model 'realistic' (assessment of look, feel and flexibility compared with a living human) and 'suitable' (assessment of suitability for learning) as a teaching model in locating the CTM by palpation or ultrasonography. Second, we compared success rates and time required to identify the CTM.

Methods

Ethical approval was provided by the Biobank and Medical Ethics Review Committee of VU University Medical Center, Amsterdam, the Netherlands. Written informed consent was obtained from all participants. All the data were collected in the anatomy laboratory of the Anatomy and Neurosciences department between April and May 2019.

Cadaver models

The cadavers were from body donors who donated their body to science via a handwritten consent, in accordance with Dutch legislation. The cadavers were embalmed with F4L fluids within 24-72 hours after death and according to the proprietary F4L embalmment protocol. Three female cadavers were made available for this study. We used female F4L cadavers because of the more challenging anatomy concerning the identification of the CTM.[5] Age at demise, weight, length, body mass index (BMI), and neck circumference were recorded. Cadavers of body donors with known neck pathology (e.g. tumour masses, goitre) or surgeries (including front-of-neck access) were excluded. The cadavers were placed in the supine position with the head in the extended position, suggested as the optimal position for locating the CTM and performing cricothyroidotomy.[1, 15, 16, 24] The correct CTM location was identified per individual cadaver in consensus of two consultant anesthesiologists and one anatomy expert using both palpation and ultrasonography techniques and marked with a dot of invisible ink, becoming visible only under ultraviolet light. The invisible marking of the CTM was covered with a 10 x 12 cm transparent dressing (Tegaderm™, 3M Healthcare, St. Paul, MN, USA) (Image 1).

Participants

Forty anesthesiology practitioners were approached as participants in the study. Inclusion criteria were at least three years of professional anesthesia practice (postgraduate 4th or 5th year of the 5-year training programme, or consultant anesthesiologist) and experience in using ultrasonography (e.g., of the airway, for peripheral nerve blocks or central venous cannula placements). Excluded were pregnant or lactating female practitioners, because of possible hazardous chemicals (including formaldehyde) in the anatomy laboratory. Characteristics of the participants (sex, age, years of experience, and number of cricothyroidotomies performed in patients) were recorded. Each participant received a standardized, brief training in the methods of ultrasonography-aided identification of the CTM, covering both the previously described 'longitudinal' and 'transverse' techniques (Images 2 and 3).[15] The participants were then allowed to practise the ultrasonography techniques on a F4L cadaver which was not included in the study. A portable ultrasound machine (Micromaxx™ Ultrasound System, Sonosite®, Bothell, WA, USA) was used. Each participant was randomly allocated to either the palpation group or the ultrasonography group using a sealed envelope technique. The participants performed the experiments individually with no other participants present.

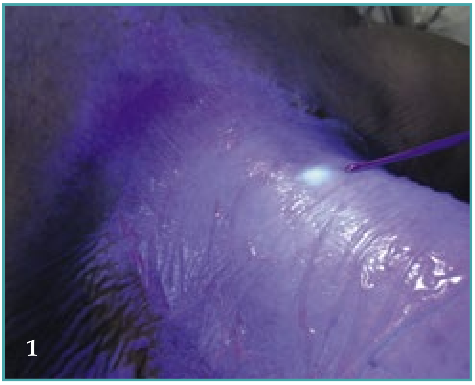
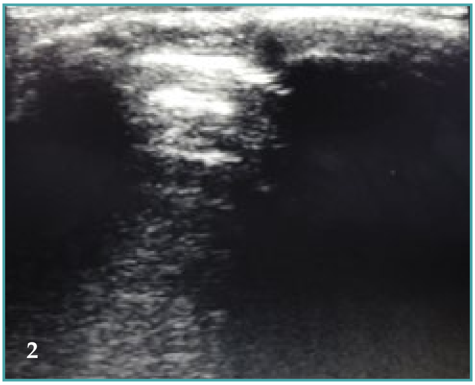
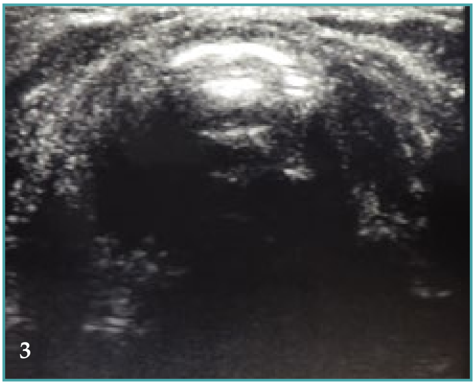


Image 1. *The invisible marking of the CTM marked with a dot of invisible ink and covered with a transparent dressing, becoming visible under ultraviolet light (Photo by Lothar Schwarte).*

Image 2. *Ultrasonographic view of the CTM using the longitudinal technique (Photo by Lothar Schwarte).*

Image 3. *Ultrasonographic view of the CTM using the transversal technique (Photo by Lothar Schwarte).*





Study Protocol

After randomisation, the participants were asked to identify the CTM in the three F4L cadavers and to mark their localisation with a blunt anatomical probe, at the point where they would puncture or incise for an actual cricothyroidotomy. The time required to identify the CTM (in seconds) was measured from the moment the participant started to palpate (palpation group) or placed the ultrasonography transducer on the neck (ultrasonography group) until the participant indicated the localisation of the CTM with the anatomical probe. The success of locating the CTM by the participants was determined by cross checking the probe's position with the predefined, anatomical position of the CTM using ultraviolet light. Successful identification of the CTM was defined as 'positive' if the participants' probe mark lay within 5 mm of the predefined location. The participants were asked to classify the difficulty of identifying the CTM per cadaver using an established four-grade system (1 = easy/visible landmarks; 2 = moderate/requires light palpation of landmarks; 3 = difficult/requires deep palpation of landmarks; and 4 = impossible/landmarks are not palpable).[11] This procedure was repeated for each of the three cadaver models in the same order. After completion of the procedures on all three cadavers, the participants of both groups were asked to give one overall verbal rating score (VRS) on a 1-10 scale (1 = worst score; 10 = best score) in two domains:

I) To rate the 'realism' of the cadaver models, compared to their professional experience with real patients by taking into account aspects such as look, feeling, tissue flexibility.
II) To rate the 'suitability' of the cadaver models in regard to their professional experience with airway simulation models and real patients, to train and teach to locate the CTM by using either the palpation technique or ultrasonography method respectively.[23, 25]

The primary outcomes were the verbal rating scores for 'realism' and for 'suitability' of the F4L cadaver as teaching model in locating the cricothyroid membrane by palpation or ultrasonography. Secondary outcomes were the success rates, time required to identify the cricothyroid membrane, and the difficulty scores.

Sample Size

We based the sample size estimation on the obtainable width of the 95% confidence interval (CI) for the estimation of 'realism' and 'suitability' (primary outcomes), and considered a margin of error of no more than 1 (= total width of the confidence interval no larger than 2) as acceptable precision. Assuming normal distribution of the data and an expected standard deviation of 2, we therefore required 18 participants in each group. Accounting for possible dropouts, we aimed at 20 participants in each group. The calculation was performed with PASS 16 (NCSS Statistical Software, Kaysville, Utah).

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp, Armonk, NY) and STATA 13.0 (STATACorp, College Station, TX). Categorical data are presented as numbers and proportions. Continuous data are presented as mean (standard deviation [SD] or 95% CI) or median (95% CI or interquartile range) where appropriate. Generalized Estimating Equations (GEE) were used to compare the groups for the primary and secondary outcomes, with professional level and experience as covariates. Significance was set at a P value of 0.05

Results

In total, 40 volunteers participated in the study: 26 consultant anesthesiologists and 14 trainees in their 4th or 5th year of the 5-year training programme. All participants were ultrasonography experienced, although not specifically regarding ultrasonography of the airway. All participants completed the experimental tasks in all three cadaver models, resulting in a total of 120 attempts, i.e., 60 attempts per group. The characteristics of the participants in both groups are summarised in Table 1. The characteristics of the three female F4L cadavers are presented in Table 2. The main results are presented in Table 3.
Participants in both the palpation and ultrasonography groups rated the F4L model high VRSs for both 'realism' and 'suitability' for training and teaching. In more detail, the ultrasonography group rated the F4L cadaver even significantly higher in both domains. The success rate in locating the CTM in the ultrasonography group was 55 out of 60 attempts (91.7%) compared to 42 out of 60 attempts (70.0%) in the palpation group (GEE: $P = 0.011$). The mean (SD) time to identify the CTM was 34.3 (27.6) s in the ultrasonography group, compared with 12.0 (6.9) s in the palpation group (GEE: $P < 0.001$). Success percentages in locating the CTM per cadaver and group are presented in Figure 1.

Table 1. Characteristics of the participants in the ultrasound (US) and palpation (PAL) groups.

	US group (n = 20)	PAL group (n = 20)	
Sex; M/F	9/11	11/9	0.201*
Age; y	40.6 (9.1)	39.7 (9.9)	0.095*
Professional experience; y	12.3 (7.1)	11.1 (8.9)	0.149*
Level; consultant/trainee, n	16/4	10/10	0.663*
≥ 1 CT** performed	2 (10%)	2 (10%)	0.000*

*Values are mean (SD), number or number (proportion). *For the comparison of baseline covariates, the absolute standardized mean difference rather than the P value is reported. **CT = cricothyroidotomy*

Table 2. Characteristics of the 3 female Fix for Life (F4L) cadaver models.

	Cadaver 1	Cadaver 2	Cadaver 3
Age at demise; y	68	90	75
Weight; kg	52	66	61
Length; m	1.70	1.67	1.66
Body mass index; kg.m-2	18.0	23.7	22.1
Neck circumference; cm	42	52	38

Table 3. Verbal rating scores (VRS) for realism and suitability of the F4L cadaver model, success rates of locating the cricothyroid membrane (CTM), mean time to identify the CTM and difficulty scores in the ultrasonography (US) and palpation (PAL) groups.

	US group	PAL group	Difference*	*P* values
VRS realism, median (95% CI)	8 (8 to 9)	8 (7 to 8)	1 (0-1)	0.001
VRS suitability, median (95% CI)	8.5 (8 to 10)	8 (8 to 8)	1 (0-1)	0.030
Success in locating CTM, *n* (%)	55 (91.7%)	42 (70.0%)	4.7 (1.4-15.6)	0.011
Time to identify CTM; (s [95% CI])	34.3 (21.4-47.2)	12.0 (8.8-15.2)	22.3 (10.2-34.5)	< 0.001
Difficulty score, median [IQR]				
Cadaver 1	2 [1-3]	2.5 [2-3]	-0.5 (-1 to 0)	0.014
Cadaver 2	2 [2-2]	3 [2-3]	-1 (-1 to 0)	< 0.001
Cadaver 3	2 [1.25-2.75]	2 [2-2.75]	0 (-1 to 0)	0.315

**The between-group difference is either the median difference for VRS and difficulty scores, the odds ratio for the success in locating the CTM, and the mean difference for the time to identify the CTM; all with 95% CI.*

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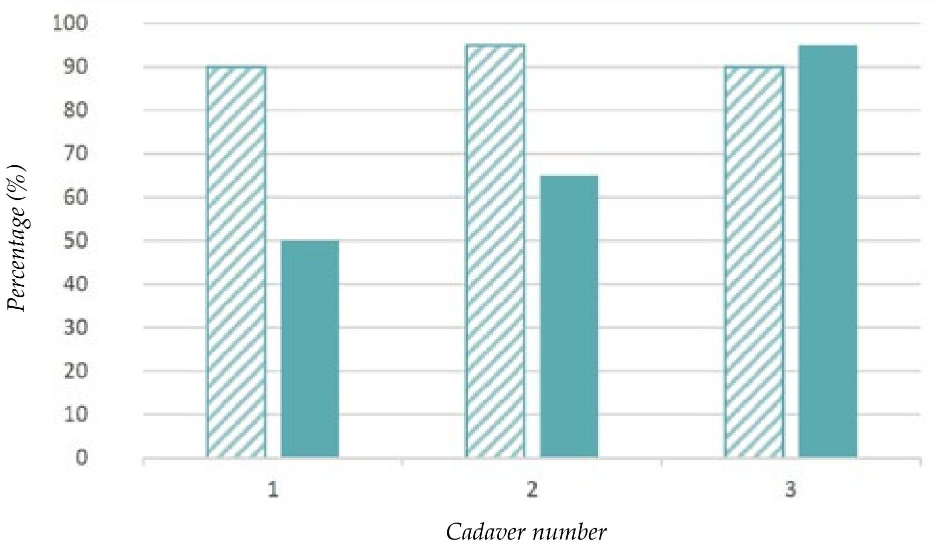

Figure 1. *Success percentages of locating the cricothyroid membrane in the 3 female F4L cadavers (numbered 1-3) in the ultrasonography (bars with dashed lines) and palpation groups (solid bars).*

Discussion

The F4L cadaver model received high VRSs for both 'realism' and 'suitability' as a teaching model for the localisation of the CTM with palpation or ultrasonography, and these scores were even higher for the ultrasonography technique. The identification of the CTM using ultrasonography in F4L cadavers was more successful compared with digital palpation. However, the time to identify the CTM was markedly longer in the ultrasonography group. Interestingly, the success rates in the ultrasonography group were already > 90% after a brief practical instruction in the use of ultrasonography in locating the CTM.

In multiple studies the reported success rates in locating the CTM using digital palpation are poor. Specifically for non-obese women, these rates have been reported to vary between 16,[7] 19.4,[6] 24,[8] 29,[5] and 71%.[9] Of these, 3 studies[5, 7, 9] also used the extended neck position as in our study, which is advised as the preferred position to locate the CTM.[1, 24] In our study, the success rate of identification with digital palpation was 70%, which was higher than we expected based on most previous studies but comparable with the result reported by You-Ten et al.[9]

Previous studies compared success rates to identify the CTM with digital palpation versus ultrasonography in two randomised groups.[10, 12, 14, 26] Ultrasonography resulted in higher success rates (ranging from 62.5-100% in the ultrasonography groups to 37-46% in the palpation groups) in several studies.[10, 12, 26] However, Yildiz et al. observed no difference in success rate (69.2% for ultrasonography against 66.7% for palpation).[14] The significantly higher success rate of 91.7% in the ultrasonography group, as well as the observed difference to the palpation group in our study, adds further evidence that ultrasonography is superior to palpation for the identification of the CTM.

Correct identification of the CTM is the first essential step in an emergency front-of-neck access situation.[1] A recently reported failure rate of 64% of front-of-neck access procedures performed by anesthesiologists[27] and complications as excess time, incision errors, tube misplacements, haemorrhage and cartilage injury occurring in 14-54.5%[19] warrants adequate training and the upkeep of skill for this procedure.

4

Moreover, cricothyroidotomy will probably be a one-time career event for most airway practitioners, even for prehospital emergency physicians.[20] In an earlier study, the F4L cadaver model was shown to be a promising teaching model for basic airway manoeuvres,[23] and with the results of the present study, the educational possibilities are expanded. Training on cadaver models can improve practitioner confidence in performing front-of-neck access[28-30] and is found to be superior to canine models.[21] Further studies will have to show if the demonstrated advantage as training model to correctly identify the CTM also holds true for the actual cricothyroidotomy procedure, compared to, e.g., 3D printed models.[31]

A study by Oliveira et al.[32] reported that after a two hour training session, most practitioners achieved competency in ultrasound-identification of the CTM. In our study, a success rate of > 90% in the ultrasonography group was achieved after a brief instruction and practise session. In light of ultrasonography being recommended as an essential tool in identifying the CTM when inspection and palpation are insufficient in individual patients,[15] this could indicate that with an even markedly shorter than two hour training session competency can be achieved. Another advantage of ultrasonography is that after practise with ultrasonography to locate the CTM, palpation skills appear to improve.[33]

The mean time to identify the CTM took markedly longer in the ultrasonography group compared with the palpation group, confirming other studies.[12, 14, 18, 26] However, in elective settings such as routine anesthesia cases, practitioners would ideally identify and mark the CTM in patients with a suspected difficult airway already before the induction of anesthesia. At that stage, time is usually not critical, and correct identification of the CTM is more important than quick identification.

The ultrasonography was performed in cadavers and the ultrasonic images could differ from live humans. In previous studies the airway sonography between live models and cadavers was found to be very similar.[12, 34] This renders the F4L cadaver a suitable ultrasonography model, and other ultrasonography training indications are yet to be determined and could extend that of the airway alone.

A large neck circumference and obesity is associated with difficult intubation and difficult identification of the CTM with palpation.[9, 35] Given the presumable advantages of ultrasonography over palpation technique in those subjects, our results would likely have been even more marked, if obese cadavers with a larger neck circumference would have been included. Confirming this assumption, in the two cadavers with a neck circumference > 40 cm, success rates in the palpation group were lower (Figure 1). Also, these cadaver models were rated as more difficult by the participants in the palpation group. On the other hand, the ease of ultrasonography seems correlated with increased neck circumference, possibly because of greater skin contact and the subcutaneous tissue can help focus the sonographic beam.[5, 9, 11]

A limitation of the study was the imbalance in baseline characteristics of the participants; however, this had no significant effect on the outcomes.

Actual cricothyroidotomies were deliberately not performed in the F4L cadaver models to maintain the individual cadavers for all participants and thus minimize interindividual model differences. In a following step, it would however be of interest to study the actual surgical cricothyroidotomies, initially by practitioners with real-life experience herein to also evaluate the suitability of the F4L cadaver model for this procedure.[20]

We defined a successful identification of the CTM if the participant located the CTM ≤ 5 mm of the predefined location. This definition of success has been used in previous studies [2, 5-7, 33, 36] and with a surgical cricothyroidotomy technique, this range is judged sufficient to locate the CTM with palpation in the subcutaneous tissue after incision.[4, 37, 38]

In conclusion, our results show that the F4L cadaver model is regarded both 'realistic' and 'suitable' to practise the identification of the CTM either by palpation or ultrasonography. A short, standardized ultrasonography training appeared to be sufficient to instruct practitioners in the use of ultrasonography to identify the CTM. Based on our observation that ultrasonography is superior to, but takes longer than, palpation to identify the CTM, we suggest pre-procedural identification of the CTM with ultrasonography in patients with a potentially difficult airway in order to act quickly in an emergency airway access situation. Since the correct identification of the CTM is recognized as the critical initial step, and gaining confidence in one's ability to correctly identify the CTM may decrease the barrier to perform cricothyroidotomy when indicated, we hope that training with the F4L cadaver model contributes to a timely, correct application of cricothyroidotomy in the future.

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CHAPTER 5

Comparison of videolaryngoscopy alone to video-assisted fibreoptic intubation in a difficult cadaver airway model

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Abstract

Background

The role of videolaryngoscopy has been recognized in difficult airway management. However, when videolaryngoscopy fails to secure a difficult airway, video-assisted fibreoptic intubation - the combination of classic videolaryngoscopy plus fibreoptic bronchoscopy - is being proposed as an alternative intubation option. In this study, we compared the effectiveness of both techniques, i.e., videolaryngoscopy and the video-assisted fibreoptic intubation combination, in a Fix for Life cadaver model with a difficult airway.

Methods

A total of 33 anaesthetists and senior trainees were randomised to the order of intubation techniques, either videolaryngoscopy or video-assisted fibreoptic intubation in the first period, and subsequently the alternate technique in the second period. Primary outcome measures were intubation success rates of both techniques. Secondary outcome measures were time until successful tracheal intubation, percentage of glottic opening scores and a verbal rating score for realism (1 = worst, 10 = best) of the cadaver model as difficult airway model.

Results

Because of a significant carry-over effect, only the results from the first period were analysed. Observed tracheal intubation success rate was higher with video-assisted fibreoptic intubation (75.0%) compared to videolaryngoscopy (41.2%), $P = 0.049$. Mean ± SD time until successful tracheal intubation was not significantly different between the two techniques, videolaryngoscopy 103.7 ± 51.7 seconds and video-assisted fibreoptic intubation 148.3 ± 71.8 seconds, $P = 0.299$. Mean ± SD percentage of glottic opening score was higher with video-assisted fibreoptic intubation 60.0 ± 37.9% versus videolaryngoscopy 29.1 ± 26.1%, $P = 0.015$. The cadaver model was scored with a mean ± SD verbal rating score of 7.6 ± 1.9.

Conclusions

Video-assisted fibreoptic intubation could be a suitable intubation aid when confronted with a difficult airway and provides a better glottic view. The cadaver model was awarded high scores for realism as a difficult airway model.

Introduction

Videolaryngoscopy (VLS) has gained widespread popularity over the past years. Its added value is particularly recognized in difficult airways, and its role has been incorporated in most difficult airway algorithms.[1, 2] However, even with VLS, intubation of the trachea can sometimes be difficult or impossible. For these situations several authors have suggested a 'dual-camera' or 'video-assisted fibreoptic intubation' (VAFI) technique,[3-7] in which the VLS is used to obtain the best possible glottic view, then held in place, while a fibrescope preloaded with a tracheal tube is introduced to intubate the trachea. This allows the practitioner the option of using both VLS and fibreoptic videoscreens for optimal vision. Recently, VAFI has been compared to VLS in patients with predictors of a difficult airway, but the results, although promising, were not conclusive as many of the patients in these studies did not actually have a difficult airway.[8, 9] In addition, predictors of a difficult airway in patients have limited diagnostic accuracy.[10-12] It is, therefore, important to compare the effectiveness of VAFI versus VLS in an established difficult airway.

Manikins can be used to simulate a difficult airway, but their airways differ significantly from human airways and extrapolating data from such studies to clinical practice is generally considered to be of limited value.[13-15] Real patients undergoing anaesthesia are also being used to simulate difficult airways, but this raises ethical concerns.[15] A third option, limiting these disadvantages, is the use of human cadavers of body donors to science.[16] A recently developed embalmment method (Fix for Life; F4L) uses minimal amounts of formaldehyde, and largely preserves the natural morphology and flexibility of human tissue.[17] In a previous study, the F4L cadaver model was found to be realistic and suitable for the training of basic airway management techniques compared to manikin and traditional formalin-fixed cadavers.[18]

The primary aim of this study was to compare intubation success rates of VAFI to VLS alone in the F4L cadaver model with an established difficult airway. Secondary outcomes were time until successful completion of the procedure, percentage of glottic opening (POGO), and a verbal rating score (VRS) for realism of the difficult airway in the F4L cadaver model.

Methods

As the Medical Ethics Review Committee of Amsterdam UMC, Vrije Universiteit (Chairperson: Prof J.A.M. van der Post), judged that this study (Reference 2019.123) did not meet the criteria of the Medical Research Involving Human Subjects Act, formal approval was waived on 6 March 2019. All participants gave written informed consent.
Prior to the start of the study, three experienced (> 10 years' experience in airway management) anaesthetists (EK, LS, PS) intubated the tracheas of multiple F4L cadaver models, donated to the department of Anatomy and Neurosciences. All cadavers were preserved according to the F4L embalmment method. To ensure a difficult airway, one cadaver on which all three anaesthetists independently scored a Cormack-Lehane (CL) grade 4 on direct laryngoscopy, was selected. Characteristics of the F4L cadaver model (age at demise, sex, length, weight, body mass index, dental status, neck circumference, thyromental and sternomental distance) were recorded.

Anaesthetists and senior anaesthesia trainees in the fourth or fifth year of the 5-year training programme participated in this randomised crossover study. Exclusion criteria were pregnant or lactating female participants, because of the possible toxicity of formaldehyde. Age, sex, years of experience, and experience with VAFI were recorded. Each participant was randomly assigned with a closed envelope technique to the order of the intubation procedures; to either first intubate the trachea with the VLS (period 1) and subsequently with the VAFI technique (period 2), or vice versa. All participants performed the procedures individually, with no other participants present at the same time.

For both intubation techniques, the VLS used was a Glidescope® (Verathon Medical, Burnaby, Canada) with an acute angled size 3 blade. For the VAFI technique, a flexible fibrescope (Ambu® aScope™ 4, Ambu A/S, Ballerup, Denmark, regular size, outer diameter 5.5 mm) was additionally provided. A regular tracheal tube size 7.0 mm (Mallinckrodt Medical, Athlone, Ireland) was used in both groups.

After randomisation, each participant was instructed to intubate the trachea using the assigned order of techniques. The participants were allowed to position the head (e.g., sniffing position) of the F4L cadaver model, according to their preference. One of the researchers acted as an assistant to provide aid, e.g., backward, upward, or rightward pressure (BURP) or jaw thrust, on request of the participant. A maximum of 5 minutes (300 seconds) was allowed per procedure. Multiple attempts were allowed within this timeframe.

The time from first introduction of the VLS into the F4L cadaver model's mouth until successful intubation of the trachea (until the tube was correctly positioned and the cuff inflated, visually confirmed on either the Glidescope® or Ambu® aScope screen) was recorded. For the VLS technique, a preformed rigid stylet (GlideRite; Verathon Medical) was used, as recommended by the manufacturer. For the VAFI technique, the tracheal tube was preloaded on the fibrescope. After the participant had obtained the best possible glottic visualization, the Glidescope was held in place by the assistant and tracheal intubation was performed with the fibrescope via the mouth. A procedure was designated a failure if the trachea was not intubated before the 300 seconds mark was reached. The percentage of glottic opening (POGO) score, as determined by the participant on the video-screen of either the Glidescope® or Ambu® aScope, respectively, was recorded.[19]

Finally, after completion of both techniques, all participants were asked to rate the F4L cadaver model for realism as a difficult airway model using a verbal rating score (VRS), in which 10 was the best possible score, and 1 the worst. A second present researcher collected all data on a datasheet.

Statistical analysis

All data were analysed with SPSS, version 26 (IBM Corp., Armonk, NY). Normality was assessed with normality plots and Shapiro-Wilk tests. To account for nonindependence, for the comparison of success rates, time and POGO scores, Generalized Estimating Equations (GEE) with an independent working correlation matrix structure and robust standard errors were used.[20] The technique and the period, as well as the interaction of period and technique were included in the model to assess main effects of the technique, the period and carry-over effects, respectively. If a significant carry-over effect was to be detected, only the technique performed in period 1 was subsequently analysed.[21] For categorical and continuous variables, the Pearson's chi-square test or Mann-Whitney U test, as appropriate, were used. For the VRSs, the mean ± SD was calculated. Significance was set at a P value of 0.05.

Sample size calculation

As reliable a priori estimates for the within-subject correlation were not available, the sample size estimation was based on a Pearson's chi-square test for two independent proportions. As cross-over designs provide higher power and thus require fewer participants than parallel-group studies, the approach may overestimate but not underestimate the required number of participants. Assuming a successful intubation rate of 60% with the VLS in this difficult airway model and an expected successful intubation rate of 90% in the VAFI group, a sample size of at least 29 participants per group is necessary to detect this difference with 80% at a 0.05 alpha level. To compensate for a potential 10% dropout, we targeted at 33 participants.

Results

Thirty-three anaesthetists and senior trainees participated in this study, of whom 15 were male and 18 were female. Mean ± SD age was 41.5 ± 9.7 years. Mean ± SD experience in airway management was 12.7 ± 8.6 years. All but one were familiar with the concept of VAFI and 19 had experience with VAFI in clinical practice. Of the participants, 17 were randomised to start with the VLS, and 16 participants started with the VAFI. The characteristics of the F4L cadaver model are presented in Table 1. Observed measurements of success rate of tracheal intubation, time and POGO scores per period are presented in Table 2. Analysis of the effect of the first intubation technique on the success of the second technique, revealed a significant carry-over effect ($P = 0.031$) (Figure 1). Consequently, we decided to exclude period 2 from the subsequent analyses of success rates, time and glottic view.

Primary outcome, success rate

In the analysis of success rates, a difference between VLS (41.2%) and VAFI (75.0%) was observed, $P = 0.049$ (Figure 2).

Intubation times

No significant difference in mean time until successful tracheal intubation was observed between both techniques (VLS 103.7 s versus VAFI 148.3 s), $P = 0.299$.

Glottic view

POGO scores were significantly higher with VAFI (60.0%) compared to VLS (29.1%), $P = 0.015$.

Subjective grading of realism

The mean ± SD VRS of all participants grading the F4L cadaver model for realism as a difficult airway model was 7.6 (1.9).

Table 1. Characteristics of the F4L cadaver model

Age at demise (years)	75
Sex	female
Length (m)	1.66
Weight (kg)	61
Body Mass Index (kg.m^{-2})	22.1
Dental status	complete
Neck circumference (cm)	38
Thyromental distance (cm)	4.5
Sternomental distance (cm)	14

Table 2. Observed outcomes of success rate of tracheal intubation, time and percentage of glottic opening (POGO) scores with the videolaryngoscope (VLS) and video-assisted fibreoptic intubation (VAFI) techniques.

	VLS	VAFI	*P***
Success rate; n			
period 1*	7 (41.2%)	12 (75.0%)	0.049
period 2	15 (93.8%)	13 (76.5%)	
Time (s)			
period 1*	103.7 ± 51.7	148.3 ± 71.8	0.299
period 2	90.8 ± 55.6	126.2 ± 69.1	
POGO score (%)			
period 1*	29.1 ± 26.1	60.0 ± 37.9	0.015
period 2	60.3 ± 26.2	71.9 ± 26.9	

Values are number (%) or mean ± SD.
**In period 1 the participant either started with VLS or VAFI. In period 2 the alternate technique was performed by the participant.*
***Because of a significant carry-over effect of performing VAFI first and VLS second, only the results of period 1 were analysed.*

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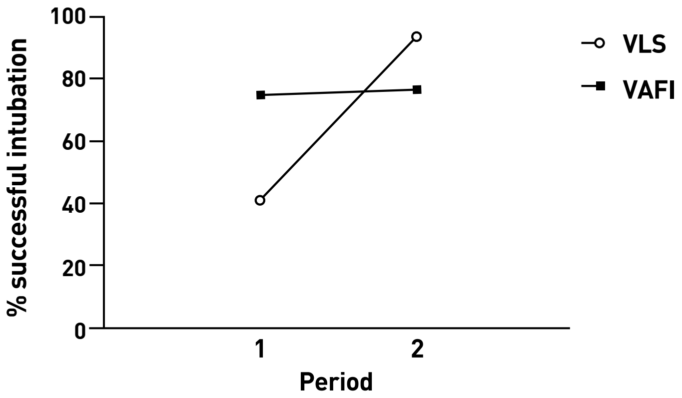

Figure 1. Carry-over effect across period 1 and 2 for the videolaryngoscope (VLS) and video-assisted fibreoptic intubation (VAFI) techniques. Participants performing VAFI in period 1 had a higher success rate with VLS in period 2 in contrast to participants who started with VLS in period 1.

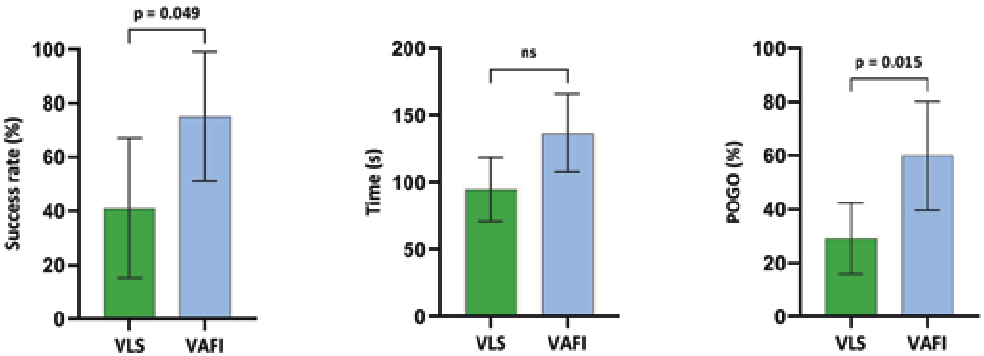

Figure 2. Observed outcomes of success rate of tracheal intubation, time in seconds until successful intubation and percentage of glottic opening (POGO) scores with the videolaryngoscope (VLS) and video-assisted fibreoptic intubation (VAFI) techniques in period 1.

Values are proportion (%), time in seconds (s). Error bars represent the 95% confidence intervals around the mean.

Discussion

In this study, 33 experienced anaesthetists and senior trainees attempted tracheal intubation in a F4L cadaver model with an established difficult airway with VLS and VAFI. Some authors recommend to use the VAFI technique in patients with a predicted difficult airway,[4, 5, 22, 23] while others even propose it should be the preferred rescue technique when faced with an unexpected difficult intubation.[7, 24] Our results show that the visualization of the glottis was markedly higher with the VAFI technique compared to VLS, which seems to translate to a higher success rate of tracheal intubation. The time until successful intubation was not different between both techniques. Overall, the F4L cadaver model received promising scores for realism as a difficult airway model.

Two recent studies compared VAFI with VLS in patients with a predicted difficult airway, e.g., patients with a Mallampati score 3 or 4, limited neck movement, or a BMI > 35 kg m^{-2}. Lenhardt et al. randomised 140 patients to be intubated with VLS or VAFI.[8] They did not find a difference in intubation success, number of intubation attempts, or time to intubation between both techniques. In the study by Mazzinari et al., the primary end point was defined as first-attempt intubation success, and this was significantly higher in the VAFI group (91%) compared to VLS (67%).[9] Also, the time until successful tracheal intubation was shorter for VAFI. Of interest is the relatively low first-attempt success rate in the VLS group in this study, although 93% of the patients presented a CL grade 1 or 2. This might be due to the authors' definition of success. Ninety-four percent of recorded failures was due to the need for a new laryngoscopy attempt, while only 6% was due to a desaturation. In our study, we defined overall intubation success as the primary end point, which we believe is more relevant when confronted with a difficult airway. Another difference is that Mazzinari et al. allowed the use of the fibrescope as a dynamic stylet only, without using its camera. In our study, participants were allowed to look at both the VLS and fibrescope screen during intubation, which we believe to be more in line with clinical practice when faced with a difficult airway. In both of these previous studies the majority (> 80%) of included patients presented a CL grade 1 or 2, making it questionable if these airways were indeed truly difficult during the VLS and VAFI procedures. As predicting a difficult airway is challenging,[10-12]

5

a major strength of our study is that we provided a true difficult airway (CL grade 4) for the anaesthetists and senior trainees. This is also illustrated by the relatively low intubation success rates.

Pieters et al. described the combination of a VLS and a rigid Bonfils intubation endoscope (BIE).[25] This was a non-randomised study where tracheal intubation was performed with a VLS and BIE in patients who presented with a CL grade 3 or 4 on direct laryngoscopy. Visualisation of the glottis was scored, first with VLS alone and again when the BIE was introduced. Similar to our study, they found that visualisation of the glottis improved when using the dual camera technique. In contrast to our study, a rigid endoscope was used. In our opinion a flexible endoscope is advantageous, since it can be directed to the glottis in a more subtle way, and therefore is less likely to cause airway injury.[26]

The participants in our study scored the F4L cadaver model high for realism of a difficult airway (> 7 on a 10-point scale), which is similar to the scores given for suitability and realism of the F4L cadaver model as a difficult airway model in an earlier study (7.7 and 7.0, respectively).[18] This is promising in providing an addition or alternative to manikins for teaching the professional management of difficult airways when a high fidelity simulator is required.[14]

Our study has several limitations. First, we used a cadaver model and not a real patient. However, in order to evaluate the benefits of a relatively new intubation technique for a difficult airway like VAFI, and to compare it to an already highly successful technique such as VLS, a pre-procedurally established true difficult airway appeared advantageous to allow for standardized observations. Since the occurrence of difficult airways is rare, and predicting them is challenging, it is difficult to conduct such a study in the general patient population. Difficult airways have been created in patients by applying a cervical collar, thereby severely restricting neck movement and mouth opening.[27-29] However, it is ethically questionable to subject otherwise easy to intubate patients to an increased risk of adverse events for the sole purpose of research.[15] We therefore decided to perform our study on a F4L cadaver model with an established difficult airway. This cadaver had undergone the F4L method of embalming, specifically developed to preserve tissue qualities in a

superior way to traditional formaldehyde fixation methods.[17]
Second, we used a single difficult airway model. We did this to standardise our study setting for all participants, but in clinical practice airways differ from patient to patient, and therefore there is no single solution for intubating all difficult airways. While tracheal intubation may proof difficult because of patient factors, such as limited mouth opening, limited neck movement, blood, secretions or tumours blocking glottic view, a difficult airway may also be the result of other factors, such as human factors (e.g. interpersonal communication), and professional experience.[30]
Third, we used only one type of VLS and endoscope device, and considering the whole range of different VLSs and endoscopes that are commercially available, the results obtained in this study cannot be directly generalized to other types. We did however employ the devices which are in standard use in practice and in our hospital.
Last, the second time point was discarded for the analysis due to a significant carry-over effect, as commonly recommended in the statistical literature.[21] However, this led to a sample size that was actually lower than the a priori calculated sample size. The limited sample size may explain the only marginally significant result for the primary outcome. While the finding of a higher success rate in the VAFI group is plausible given the higher POGO scores, these results should be interpreted with care and should be confirmed in further research.

In conclusion, our results show that the majority of a group of experienced airway practitioners was able to intubate a difficult airway in a F4L cadaver model with the VAFI technique. Our findings suggest that intubation success is higher with VAFI compared to VLS, which is probably due to the improved glottic view. However, further research is needed to confirm these findings. The F4L cadaver model could be a suitable alternative for manikins in providing a teaching model for difficult airway management.

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CHAPTER 6

Summary and general discussion

The primary focus of this thesis was the novel Fix for Life (F4L) cadaver model and its possible role in airway management training. In this chapter, an overview of the results obtained from the different studies is presented and discussed. Concluding remarks and possibilities for further research will be provided at the end of this chapter.

The following research questions were addressed:

1. Is the F4L cadaver model a suitable and realistic model for the training and teaching of different airway management techniques?
2. How suitable and realistic is the F4L cadaver model for the training of the identification of the correct anatomical spot to incise for a 'surgical airway' (cricothyroidotomy), i.e., the identification of the cricothyroid membrane via palpation and ultrasonography?
3. What is the effectiveness of video-assisted fibreoptic intubation versus videolaryngoscopy in an established difficult airway F4L cadaver model?

Is the F4L cadaver model a suitable and realistic model to train and teach different airway management techniques?

In **Chapter 2**, F4L cadaver models were compared to formalin-fixed cadaver models and a manikin for suitability and realism for the teaching of 3 basic airway skills: facemask ventilation, tracheal intubation via direct laryngoscopy, and laryngeal mask insertion. Thirty anesthesiologists and senior trainees were included as participants and performed these procedures. Primary outcomes were the total rank the participants gave the different models, i.e., the participants had to rank the model they found best as 1st, their second best model as 2nd and their third best model as 3rd. In addition, the participants ranked the type of model per technique. Finally, the participants gave a verbal rating score for suitability (defined as the participant's assessment of the suitability of the model for the teaching of the airway maneuver to a novice), and for realism (defined as the participant's assessment of the realism of the model regarding look, feel and flexibility compared to real patients). Secondary outcome measures were the success rates in completing the different airway maneuvers per model.

The F4L cadaver model was ranked best for mask ventilation in comparison with the formalin-fixed cadaver and the manikin. In other rankings, the F4L cadaver model was not ranked significantly different in regard to the manikin. Both the F4L cadaver model and the manikin were ranked significantly higher than the formalin-fixed cadaver model. With the exception of the score for realism of laryngeal mask insertion, all verbal rating scores between the F4L cadaver model and the manikin for suitability and realism of the different techniques, were not significantly different. The formalin-fixed cadaver model received the lowest scores. Success rates were highest in the manikin, followed by the F4L cadaver model. Based on these results, we concluded that there is potential of the F4L cadaver model in airway management training, and it seems particularly useful for training mask ventilation.

Looking more closely at the verbal rating scores given by the participants, it is of interest to note that none of the scores were above 7.5. The highest verbal rating score for the F4L cadaver model was 7.2 (for suitability for mask ventilation), while for the manikin this was 7.4 (also for suitability for mask ventilation, this score did not differ significantly from the F4L cadaver model). The highest verbal rating score for the formalin-fixed cadaver model was 3.4 (also for suitability for mask ventilation). Interestingly, for laryngeal mask insertion, neither the F4L cadaver model or the manikin received high scores (all the scores given for realism and suitability regarding laryngeal mask insertion did not exceed 5.0), albeit the F4L cadaver model was found to be the most realistic of the two. If 10 is a perfect score, resembling the real patient most closely, we could deduce that the F4L cadaver model is considered reasonably well, particularly for mask ventilation as mentioned earlier. For tracheal intubation, these scores were reasonable for the F4L cadaver model and manikin alike, while the formalin-fixed cadaver was obviously found to be inappropriate. We hypothesize that these scores reflect the discrepancy between model and real patient.

In the case of the F4L cadaver model, a possible explanation lies in the fact that this model was more rigid than anticipated from our preliminary experiments. This was also reflected in the higher Cormack-Lehane grades reported and the higher need for assistance, such as ‘backward upward rightward pressure’ (BURP) and the use of an intubating catheter. A possible explanation could be the amount of formaldehyde used in the F4L embalming method, even though it is a significantly reduced amount compared to the traditional embalming method. However, since this first study, efforts have been made to further reduce the amount of formaldehyde, while still provide for a well-conserved cadaver model. Another reason could be that there are inherent differences between the cadavers the department receives for fixation. For instance, there could be a shorter or longer post-mortem delay until embalming, anatomical differences of the donor, e.g., pre-existing flexibility, or reaction of the body to and subsequently quality of the embalmment itself. For the manikin, we believe the lesser similarity with a real patient, i.e., being made of synthetic material, and not reflecting human anatomy closely is the reason for these scores. This is supported, for example, by a study examining the anatomy of high-fidelity manikins, which concluded that most of these manikins do not reflect upper airway anatomy as found in real patients.[1]

Mask ventilation is an essential skill for every airway practitioner, and the learning curve to master this technique efficiently can show slow progress.[2-4] Therefore, it is of interest that the F4L cadaver model was ranked significantly higher (i.e., ranked better as teaching model) than the manikin. The incidence of difficult mask ventilation is described as in the range of 0.08% to 15%, with predictors of difficult mask ventilation being the presence of a beard, obesity, older age, and lack of teeth.[5-7] In contrast to a manikin, the F4L cadaver could provide all these aspects, and thereby create optimal learning scenarios to train to manage difficult mask ventilation.

Several cadaver models have been described as useful for airway management training. These range from fresh frozen to Thiel embalmed cadaver models.[8-14] In the study by Szűcs et al the Thiel embalmed cadaver model received very high verbal rating scores for mask ventilation (9.0) and for tracheal intubation (8.0).[9] These scores a higher compared to our results, but it should be noted that the scores given to the manikins were also lower compared to our study: 4.2 for mask ventilation and 5.9 for tracheal intubation. These differences in scores regarding the cadaver model perhaps could be explained by a higher flexibility of the Thiel embalmed cadaver model, even though it is an embalming method which also requires minimal amounts of formaldehyde.[15, 16] A major advantage of the F4L cadaver model is the fact that after embalming it is immediately available for use, while in the Thiel embalming method the cadaver needs to be submerged in fluid for at least two months prior to use. Interestingly, a recent study describes the Thiel embalmed cadaver as a physiological model, in which experimental ventilation and intrathoracic pressure during cardiopulmonary resuscitation were assessed.[17] It could be of interest to study the F4L cadaver model for similar purposes.

Considering the reported realism and suitability of the F4L cadaver model for the training and teaching of mask ventilation, tracheal intubation through direct laryngoscopy and laryngeal mask insertion, it can be concluded that the model could be of relevance, particularly in the training of mask ventilation. A training curriculum, in which the manikin and F4L cadaver model are both available to trainees could provide for a beneficial learning environment. Given the promising scores for suitability of the F4L cadaver model for difficult airway management, we decided to do a follow up study.

In **Chapter 3**, the assessment of the F4L cadaver model for two advanced airway techniques, namely tracheal intubation with videolaryngoscopy and flexible fibreoptic tracheoscopy, is presented. In this study, the primary objective were the verbal rating scores for suitability and realism of the F4L cadaver model for the teaching of these two tracheal intubation maneuvers to novices in airway management. The secondary objectives were the success rates and the time taken to successfully complete these procedures. To this end, forty anesthesiologists and senior trainees performed these techniques in four F4L cadaver models.

The verbal rating scores for suitability of the model was above 8 for both techniques, and above 7 for realism. The success rates were near 100%. The results in verbal rating scores were very promising, as these were higher compared to the scores described in Chapter 1, indicating that the F4L cadaver model could be more suitable for these advanced techniques. This is also illustrated by the success rate of 60% of tracheal intubation through direct laryngoscopy in the prior study. As most of the F4L cadaver models included in the studies have a Cormack-Lehane grade > 1, this seems plausible. These results suggest that the F4L cadaver model could be regarded as a suitable and realistic training model for videolaryngoscopy and flexible fibreoptic tracheoscopy, particularly for the more challenging airway.

The use of videolaryngoscopy as the standard intubation tool, as well as for the difficult airway is increasingly advocated.[18-20] While some studies report an increased success rate of tracheal intubation with videolaryngoscopy by novices,[21, 22] other studies report a prolonged training and practice time needed to accomplish competency in the technique.[23] While manikins have been described as useful in the learning of videolaryngoscopy,[24] the discussion on the reality of the anatomy of manikins remains an issue.[1, 25] We believe the F4L cadaver model could provide for a suitable and realistic alternative, based on our investigation.

Fibreoptic tracheoscopy has been propagated as one of the main techniques of choice when a difficult airway has to be safely intubated.[26-28] Simple and effective models have been described to learn this technique, as well as virtual simulators and animal models.[27, 29-32] As these are training tools often dedicated to this technique alone, we hypothesize that the F4L cadaver can offer additional benefits of practicing multiple techniques in one session, when so required.

Since the introduction of videolaryngoscopy, suggestions are being made to use this technique instead of (awake) fibreoptic tracheoscopy.[33, 34] As a consequence, a discussion has arisen about the opportunity trainees in anesthesia have to acquire and maintain the skill of fibreoptic tracheoscopy, as it has become apparent that with the introduction of videolaryngoscopy, the use of fibreoptic tracheoscopy has reduced.[35] A study described Thiel embalmed cadaver models as beneficial in the training of the technique, when compared to manikins.[36] Utilizing the F4L cadaver model in similar fashion as training model, imaginably in addition to other training models, could provide for opportunities in the upkeep of this skill.

An obvious disadvantage of the F4L cadaver model is that the circumstances for awake fibreoptic intubation cannot be simulated, a drawback other bench models and manikins share. However, the main advantage of the F4L cadaver model is the possibility to practice the technique with rather realistic anatomical views, as well as no time constraints, or chance for injury as encountered in clinical practice.

How suitable and realistic is the F4L cadaver model for the training of the identification of the correct anatomical spot to incise for a 'surgical airway' (cricothyroidotomy), i.e., the identification of the cricothyroid membrane via palpation and ultrasonography?

The crucial initial step when confronted with a 'can't intubate can't oxygenate' situation, is the identification of the cricothyroid membrane.[19] This has proven to be challenging for many practitioners, with reported correct identification rates ranging between 0-72% depending on sex, body habitus, as well as position of the neck.[37-47] Since the failure rate of cricothyroidotomy performed by anesthesiologists has proven to be relatively high,[48] and reported complications include excess time, incision errors, tube misplacements, haemorrhage and cartilage injury in 14-54.5% of cases, upkeep and regular training of this skill seems warranted.[49] This is further stressed by the low reported incidence of performed cricothyroidotomies and self-reported confidence in doing so, as well as the decreasing competency in this technique with increasing age of the practitioner.[50, 51]

Chapter 4 described the suitability and realism of the F4L cadaver model for the training of the identification of the cricothyroid membrane with palpation or ultrasonography. Additionally, success rates and time until successful identification of the cricothyroid membrane of both techniques were studied. Forty anesthesiologists and senior trainees were randomized to identify the cricothyroid membrane either by palpation or with ultrasonography in three female F4L cadaver models. We chose female F4L cadavers deliberately because of the more challenging anatomy concerning the identification of the CTM.[38]

The F4L cadaver model received high verbal rating scores for both techniques, being 8 or higher. The rate of successful identification was significantly higher in the ultrasonography group, although the time needed to do so was longer. We concluded that the F4L cadaver model is realistic and suitable to train the identification of the cricothyroid membrane.

Ultrasonography has proven to be beneficial in the identification of the cricothyroid membrane,[52] but just as we have found in our study, the time needed to correctly identify the cricothyroid membrane is usually longer.[40, 41, 46] Therefore, it is suggested to identify the cricothyroid membrane pre-procedurally.[53] Naturally, this does not apply to emergency situations, such as out-of-hospital trauma care.[54]

We did not study the performance of the actual cricothyroidotomy in the F4L cadaver, which would be of interest, as benefits of learning the procedure on cadavers have been reported.[10, 12, 55, 56] Numerous models are described as efficient for the training of this procedure, but not all of these reflect human anatomy as closely as the F4L cadaver model.[57-59] As obesity is associated with increased difficulty in the identification of the cricothyroid membrane, as well as the performance of cricothyroidotomy, the selection of obese cadaver models could provide for an optimal practice session to train with these challenging circumstances.[60, 61] A disadvantage of the F4L cadaver model, or any cadaver model, is that one can only perform front-of-neck access only once, after which the anatomy is evidently disturbed. However, the F4L cadaver models could be used by more participants in the training of the crucial initial step, namely the identification of the cricothyroid membrane by palpation and ultrasonography, after which some of them could have the opportunity to perform an actual cricothyroidotomy. Furthermore, instructional videos could be made of the procedure, for prior or later reference by trainees.

What is the effectiveness of video-assisted fibreoptic intubation versus video-laryngoscopy in an established difficult airway F4L cadaver model?

The study described in **Chapter 5** primarily compared the success rates of tracheal intubation with videolaryngoscopy versus video-assisted fibreoptic intubation in a difficult airway F4L cadaver model. Secondarily, the time until successful tracheal intubation and the percentage of glottic opening scores were assessed, and a verbal rating score regarding the realism of the F4L cadaver model as difficult airway model was obtained. Thirty-three anesthesiologists and senior trainees were randomized to the order of intubation techniques. The participants either started with videolaryngoscopy and subsequently performed the video-assisted fibreoptic intubation, or vice versa.

The success of tracheal intubation was higher with the video-assisted fibreoptic intubation technique compared to videolaryngoscopy alone. This was probably due to the higher percentage of glottic opening visible with the video-assisted fibreoptic intubation technique. The time until successful tracheal intubation was not significantly different between the two techniques. The F4L cadaver model was awarded high scores for realism as a difficult airway model.

It is of interest to study new airway management techniques or devices. Patients undergoing anesthesia are being used, e.g., on whom a rigid cervical collar is placed during intubation in order to simulate a more difficult airway.[62, 63] However, this is not without its ethical considerations.[64] As mentioned previously, manikins are also used extensively in airway management research, but not without their limitations.[65] For this reason, cadaveric specimens such as the F4L cadaver model could be an interesting alternative to study airway management techniques and devices.[66]

The combined use of the videolaryngoscope and a fibreoptic tracheoscope or bronchoscope as movable stylet, thereby reducing the risk of intubation trauma, has been described previously.[67, 68] In multiple case series this technique has been suggested to be helpful for the tracheal intubation of patients who presented with a difficult airway, and is being proposed as rescue strategy.[69-74] The technique has also been proposed for educational purposes in learning fibreoptic intubation.[75] Several studies evaluated the technique in patients with predictors of a difficult airway, and found the technique just as effective as when using videolaryngoscopy alone, or more beneficial when the cervical spine was immobile.[76, 77] Although these studies included patients with predictors of difficult intubation, the majority actually presented a Cormack-Lehane grade ≤ 2 during the intubation procedures. This could be explained due to the fact that predicting a difficult intubation appears to be challenging.[78] For this reason, we selected a F4L cadaver model with a Cormack-Lehane grade 4 (neither glottis or epiglottis visible) on direct laryngoscopy, thereby ensuring a “true” difficult airway for the participants. Not all previous studies report the use of both screens by the practitioner, i.e., the video screen of the videolaryngoscope as well as the video screen of the flexible tracheoscope. Some studies describe only using the video screen of the videolaryngoscope, while using the flexible tracheoscope as a movable stylet visible on the video screen of the videolaryngoscope.[77] In our study we did allow the participant the use of both video screens. We believed this allowed for optimal visualization of the glottis.[68]

A significant carry-over effect was detected in the analysis of this cross-over study.

Due to this fact, the second period, in which the participant performed the alternate technique, was disregarded for further analysis. In doing so, the power of the study was affected. Nevertheless, the results showed that the POGO scores were significantly higher when using the video-assisted fibreoptic intubation technique compared with videolaryngoscopy alone, which could explain the higher success rate. Since this conclusion had to be drawn with caution, further studies are appropriate to confirm the findings. To prevent carry-over effects in the future, we propose a different study design of two independent groups, or possibly a longer 'wash out' period between performing both techniques.

Concluding remarks

In this thesis, the F4L cadaver model has been the focus of our different investigations into the possible realism and suitability for airway management training and the comparison of two intubation techniques for a difficult airway. Based on our studies, the following conclusions can be drawn:

1. The F4L cadaver model could be a suitable and realistic alternative model to the manikin for the training of basic airway maneuvers, in particular for mask ventilation.
2. The F4L cadaver model is a suitable and realistic model for the teaching of advanced airway procedures, namely videolaryngoscopy and fibreoptic intubation.
3. The F4L cadaver model is a suitable and realistic model for the teaching of cricothyroid membrane identification via palpation and ultrasonography.
4. The higher visible percentage of glottic opening obtained with the video-assisted fibreoptic intubation technique versus videolaryngoscopy, probably translates to a higher intubation success in a difficult airway.

While the translational value of procedural skills learned on cadaver models has yet to be definitively established,[79-81] there are indications that trainees obtain more confidence and report superior learning experience when learning these skills on cadaver models.[10, 82-84] Especially considering the maintaining of skills and the training of procedures not regularly encountered in practice,[50, 85] a cadaver model, such as the F4L cadaver model could provide for a suitable and realistic training model.[82, 86]

Limitations of the F4L cadaver model are the relatively higher age of the donors at demise, which makes the body habitus not generalizable to younger patients encountered in practice. Although costs have not been specifically mentioned, these are considerable and include an infrastructure and personnel needed to maintain an anatomical facility. Also, not every anatomy body donation program will use the F4L solution, as there are many different soft-fixation embalming methods available. With the use of embalmed human tissue, there are always infection and hazardous substances risks to be considered, and the necessary precautions taken to reduce those risks. As some modern manikins have the possibility to simulate breathing, heart rhythm and such, these are obvious aspects a F4L cadaver model cannot provide, and as such is less suited for scenario training in which actual vital parameters of a patient are being simulated.

In the abundance of models, manikins, and simulators already available, it is perhaps more realistic to consider the F4L cadaver model an addition to this arsenal. The variation of the anatomy and habitus of the different cadaver models (in particular obesity), the possibility to perform invasive procedures (such as cricothyroidotomy or thoracotomy) and other ultrasonography guided procedures, such as regional anesthesia techniques, could provide for even more options. These are aspects of interest to be studied in the future. Other possibilities for further research could include the translation of skills learned on the F4L cadaver model to the actual patient.

From the anatomist's view point, it is of interest to investigate whether a cadaver model, such as the F4L cadaver model, is of particular use in postgraduate medical training. As the hours spent on anatomy teaching in medical schools are significantly less compared to earlier years, and the time medical students are allowed to dissect a human cadaver in order to study anatomy has become less, postgraduate procedural training for medical professionals on human cadavers is becoming more prominent.[87] To provide for the most optimal training or simulation experience, a cadaver model with as much realistic tissue properties mimicking the real patient is desired.[82] In regard to postgraduate airway management training, the F4L cadaver model seems very promising. Especially compared to the traditional formaldehyde-fixated cadaver, the F4L cadaver model is a definitive improvement. However, with the abundance of other soft-fixating embalming methods used worldwide, no conclusions can be drawn in regard to the performance of the F4L cadaver model for procedural training in comparison to these other embalming methods.

In the future of anatomical education, it is plausible that in undergraduate medical training, the focus for medical students shall continue to be based on anatomy demonstrations and independent studying, using specifically prosected anatomical specimens to understand the basics of clinically relevant anatomy, for instance in relation to radiological images. For the more anatomically or surgically interested student, special targeted courses offering dissection should be kept available. The more extensive dissection and procedural training sessions are then reserved for the surgical and other trainees of disciplines (e.g., anesthesiology or dermatology) who need a more clinical anatomical comprehension of specified areas of the human anatomy. This additional anatomical comprehension on top of their basic clinical anatomical knowledge is necessary to safely and knowledgeably perform surgical or other invasive procedures. Another possible option would be an extensive anatomy course at the start of postgraduate training for all those trainees needing specific additional anatomical comprehension. For these reasons, it could also be of interest to study the effectiveness of the F4L cadaver model for different surgical and other procedural training. These studies could increase the validity of the F4L cadaver model, could help improve the embalming method, or adjust it to the specific requirement of a certain procedure. Hopefully, this will lead to the most optimal usage, and learning of students and professionals from this great gift of the body donor.

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6

CHAPTER 7

Nederlandse samenvatting

Luchtwegmanagementtechnieken zijn cruciaal in bijvoorbeeld de medische specialismen van de anesthesiologie, intensive care en spoedeisende hulp. Voorbeelden van deze technieken zijn kapbeademing, intubatie en het inbrengen van een larynxmasker. Technieken die gebruikmaken van camera's om de luchtweg van de patiënt in beeld te brengen, zijn videolaryngoscopie en de flexibele fiberoptische of videoscopische laryngo-tracheoscopie. Historisch gezien werden deze technieken aan beginnende professionals aangeleerd op patiënten die bijvoorbeeld onder narcose gingen, waar zich ethische en medico-legale problemen bij voor kunnen doen. Daarnaast zijn er diverse synthetische modellen op de markt die voor het aanleren van luchtwegmanagementtechnieken gebruikt kunnen worden. Echter, synthetische modellen zijn veelal van kunststof gemaakt en het simuleren van hoe de 'echte' patiënt aanvoelt, en de variatie in de anatomie die er bestaat tussen de mensen, is moeilijk na te bootsen. Op lichamen van pas overleden patiënten kan ook geoefend worden, maar daar kleven ook ernstige ethische bezwaren aan. Een andere optie is het gebruik van aan de wetenschap gedoneerde lichamen. Dit zijn lichamen van lichaamsdonoren die na hun overlijden hun lichaam beschikbaar hebben gesteld aan één van de anatomische afdelingen. Meestal worden deze lichamen gebalsemd om te gebruiken in het anatomisch onderwijs aan medisch studenten. Het lichaam niet balsemen kan ook (vers bevroren). Hiermee behoud je veelal het 'weefselgevoel' zoals je dat in de levende patiënt ook aantreft. Het grote nadeel is uiteraard de verdergaande ontbinding, waardoor de tijdspanne waarin het lichaam te gebruiken is, kort is. De gebruikelijke balsemmethode is door middel van een balsemvloeistof met als hoofdbestanddeel formaldehyde. De conservering van het lichaam is hierbij optimaal, maar een nadeel is dat het lichaam rigide wordt. Een ander nadeel zijn de giftige eigenschappen van formaldehyde, waardoor het werken in een omgeving gevaarlijk kan zijn, voor bijvoorbeeld zwangeren. Recent is er een nieuwe balsemmethode ontwikkeld, 'Fix for Life' (F4L), waarbij aangenomen wordt dat de weefselkwaliteit van het geconserveerde lichaam nagenoeg hetzelfde is als van de levende patiënt. In deze methode wordt een sterk gereduceerde hoeveelheid aan formaldehyde gebruikt, naast andere bestanddelen, wat bij gebruik van het lichaam in het anatomisch laboratorium niet gevaarlijk zou zijn voor de professional. Dit zou kunnen betekenen dat dit nieuwe F4L-lichaamsmodel uitermate geschikt zou kunnen zijn voor het oefenen van luchtwegmanagementtechnieken of andere invasieve dan wel chirurgische ingrepen. Het belangrijkste doel van dit proefschrift is het beschrijven van het realisme en de geschiktheid van het F4L-lichaamsmodel voor het aanleren van luchtwegmanagementtechnieken.

In de verschillende hoofdstukken van dit proefschrift worden de belangrijkste onderzoeksvragen die wij hebben gepoogd te beantwoorden besproken:

1. Is het F4L-lichaamsmodel een geschikt en realistisch model voor het trainen en onderwijzen van verschillende luchtwegmanagementtechnieken?
2. Hoe geschikt en realistisch is het F4L-lichaamsmodel voor het leren identificeren van het ligamentum cricothyroideum (een plekje voor in de hals, tussen verschillende delen van het strottenhoofd, alwaar indien noodzakelijk een toegang gemaakt kan worden tot de luchtweg bij acute respiratoire insufficiënte die niet via de gangbare nasale of orale route veiliggesteld kan worden) door middel van palpatie of met echografie?
3. Wat is de effectiviteit van intubatie door middel van videolaryngoscopisch geassisteerde fiberoptische intubatie versus alleen videolaryngoscopie in een moeilijke luchtweg?

Hoofdstuk 1 van het proefschrift is de algemene introductie en beschrijft bovenstaande achtergrond en de onderzoeksvragen.

In **hoofdstuk 2** wordt het onderzoek beschreven waarin we hebben gekeken naar de geschiktheid en het realisme van het F4L-lichaamsmodel in vergelijking met de formaldehydegefixeerde lichamen en een synthetisch luchtwegmodel. In dit onderzoek werden 30 anesthesiologen en artsen in opleiding tot specialist (AIOS) anesthesiologie gerandomiseerd voor de volgorde waarin zij op de 3 verschillende modellen, te weten kapbeademing, intubatie door middel van directe laryngoscopie en het inbrengen van een larynxmasker uitvoerden. De primaire uitkomstmaten waren de ranking die de deelnemers gaven (van 1ste tot 3^{e} plaats) aan de verschillende modellen als trainingsmodel voor deze luchtwegtechnieken, alsmede de ranking van de verschillende modellen per techniek (kapbeademing, intubatie en inbrengen larynxmasker) en ten slotte de verbale ranking score (VRS) op een schaal van 1 tot 10 voor de verschillende technieken per model (1 = totaal niet geschikt of realistisch in vergelijking met de echte patiënt; 10 = volledig geschikt of realistisch in vergelijking met de echte patiënt). Secundaire uitkomstmaten waren de succespercentages van de uit te voeren procedures per techniek en model. De mediane totale ranking die de deelnemers aan de verschillende modellen gaven, was 1 voor het F4L-lichaamsmodel, 2 voor het synthetische model en op 3 het formaldehydegefixeerde lichaam. Het F4L-lichaamsmodel werd beschouwd als het beste model voor de kapbeademing en kreeg een hogere VRS voor realisme voor het inbrengen van een larynxmasker. De F4L-lichaamsmodellen en het synthetische model verschilden op overige punten niet significant voor wat betreft ranking of VRS's. De formaldehydegefixeerde lichamen kregen de laagste ranking en de laagste VRS's. De succespercentages van de verschillende technieken waren het hoogst op het synthetisch model. Op basis van dit onderzoek concludeerden wij dat het F4L-lichaamsmodel geschikt en realistisch wordt geacht voor het trainen van luchtwegtechnieken. Formaldehydegefixeerde lichamen zijn hiervoor niet geschikt.

Op basis van de resultaten van het onderzoek zoals beschreven in hoofdstuk 1, werd het interessant geacht te onderzoeken hoe geschikt dan wel realistisch het F4L-lichaamsmodel zou zijn voor meer geavanceerde luchtwegtechnieken, te weten videolaryngoscopie en de flexibele fiberoptische laryngo-tracheoscopie (in het onderzoek werd gebruikt gemaakt van een flexibele 'video-endoscoop', echter voor het verduidelijken van het onderscheid met de videolaryngoscoop wordt hier ook wel de term 'fiberoptische scopie' gebruikt). Dat onderzoek wordt in **hoofdstuk 3** uiteengezet. De videolaryngoscopie wordt steeds meer aanbevolen als standaard intubatiemethode, terwijl de fiberoptische intubatie grofweg gezien wordt als de gouden standaard voor de moeilijke luchtweg. Voor dit onderzoek werden 40 anesthesiologen en AIOS anesthesiologie benaderd. Zij werden geïnstrueerd om de intubatie op de F4L-lichaamsmodellen uit te voeren door middel van deze twee technieken. De primaire uitkomstmaat waren de VRS's (op dezelfde schaal van 1 tot 10 zoals gebruikt in hoofdstuk 2) voor realisme en voor geschiktheid van het F4L-lichaamsmodel als trainingsmodel voor deze technieken. Secundaire uitkomstmaten waren het aantal succesvol uitgevoerde procedures en de tijd die nodig was voor succesvolle intubatie. Het F4L-lichaamsmodel kreeg voor beide technieken hoge VRS's voor geschiktheid (> 8) en realisme (> 7). Alle videolaryngoscopieprocedures waren succesvol, terwijl dat aantal voor de fiberoptische intubatie erg hoog was (> 95%). De tijd die nodig was voor succesvolle intubatie, bevond zich hoofdzakelijk binnen reeds eerder gerapporteerde tijdsduren van deze procedures op patiënten. De belangrijkste conclusie van dit onderzoek was dat het F4L-lichaamsmodel een geschikt en realistisch trainingsmodel is voor het aanleren van videolaryngoscopie en fiberoptische intubatie.

Het onderzoek dat beschreven staat in **hoofdstuk 4** betreft de geschiktheid en realisme van het F4L-lichaamsmodel als trainingsmodaliteit voor het identificeren van het ligamentum cricothyroideum aan de voorzijde van de hals, tussen verschillende delen van het strottenhoofd. Deze anatomische locatie kan dienen als toegangsweg tot de luchtpijp indien de normale route via de mond of neus niet mogelijk is en de patiënt in acute ademnood is. De identificatie van deze plek kan plaatsvinden door middel van palpatie (het voelen met de vingers), maar dat blijkt uit de literatuur onbetrouwbaar, met name bij patiënten met overgewicht of bij vrouwelijke patiënten. Een andere mogelijkheid is de identificatie door middel van ultrasonografie (echografie). Deze techniek wordt beschreven met een veel hogere kans op succes. In het onderzoek werden de 40 deelnemende anesthesiologen en AIOS anesthesiologie gerandomiseerd om het ligamentum cricothyroideum te identificeren door middel van palpatie of door ultrasonografie op drie vrouwelijke F4L-lichaamsmodellen. De primaire uitkomstmaten waren de VRS's (op de schaal van 1-10) gegeven door de deelnemers voor geschiktheid en realisme van het F4L-lichaamsmodel als trainingsmodel voor het leren identificeren van het ligamentum cricothyroideum door middel van palpatie of ultrasonografie. Secundaire uitkomstmaten waren de succespercentages en de tijd die nodig was tot succesvolle identificatie. Voor beide technieken ontving het F4L-lichaamsmodel hoge scores voor realisme en geschiktheid (> 8), alhoewel statistisch gezien de scores voor de ultrasonografie nog iets hoger waren. In 70% van de gevallen was de identificatie met palpatie succesvol, terwijl dat door middel van de echo met ruim 91% significant beter was. Echter, de tijd die het duurde eer het ligamentum cricothyroideum correct werd geïdentificeerd, duurde langer wanneer ultrasonografie gebruikt werd. De voornaamste conclusie van het onderzoek was dat het F4L-lichaamsmodel uitermate geschikt is als onderwijsmodel voor het leren identificeren van het ligamentum cricothyroideum. Ook de superioriteit van de ultrasonografie voor dit doeleinde konden we beamen. Met name de kans om in de toekomst dan ook daadwerkelijk het krijgen van toegang tot de luchtweg te oefenen, wordt gezien als een groot voordeel het F4L-lichaamsmodel.

Hoofdstuk 5 richt zich op de vergelijking van de intubatie van een moeilijke luchtweg in een F4L-lichaamsmodel door middel van videolaryngoscopisch geassisteerde fiberoptische intubatie versus videolaryngoscopie alleen. De rol van videolaryngoscopie bij een moeilijke luchtweg wordt al langer onderkend. Echter, op momenten dat videolaryngoscopie alleen niet voldoende is om de luchtweg te intuberen, wordt een andere techniek voorgesteld. Deze techniek is de videolaryngoscopisch geassisteerde fiberoptische intubatie. In deze techniek krijgt de anesthesioloog eerst met de videolaryngoscoop het beste mogelijke zicht op de luchtweg in beeld. Vervolgens neemt een tweede professional de videolaryngoscoop over en houdt het beeld stabiel, zodat de anesthesioloog een flexibele laryngo-tracheoscoop, waaroverheen een beademingsbuis geplaatst is, kan inbrengen. Door middel van het zicht van zowel de videolaryngoscoop, alsmede de flexibele laryngo-tracheoscoop, kan de anesthesioloog vervolgens de luchtweg intuberen door de beademingsbuis af te schuiven van de flexibele laryngo-tracheoscoop. Voor dit onderzoek werd een F4L-lichaamsmodel geselecteerd met een moeilijke luchtweg, dat wil zeggen, bij directe laryngoscopie werden geen onderdelen van de toegang tot de luchtpijp gezien. In totaal werden 33 anesthesiologen en AIOS gerandomiseerd voor de volgorde waarin zij deze 2 technieken op het model uitvoerden (een zogenaamde cross-over studie). Primaire uitkomstmaat was het succesvolle aantal intubaties van beide technieken. Secundaire uitkomstmaten waren de tijd tot succesvolle intubatie, het percentage aan zicht op de toegang tot de luchtpijp en ten slotte een VRS (schaal 1-10) voor realisme van het F4L-lichaamsmodel ten aanzien van de moeilijke luchtweg. Tijdens de analyse van de resultaten bleek dat het uitvoeren van de eerste techniek een significant effect had op het uitvoeren van de tweede techniek. Vanwege dit zogenaamde 'carry-over effect' werd besloten alleen de resultaten van de door de deelnemers in eerste instantie uitgevoerde techniek te analyseren. De geobserveerde succesvolle intubaties waren met 75% een stuk hoger met de videolaryngoscopisch geassisteerde fiberoptische intubatie versus videolaryngoscopie alleen (ruim 41%). De tijd tot succesvolle intubatie was niet significant verschillend, maar het zicht op de toegang tot de luchtpijp was wel een stuk hoger met de videolaryngoscopisch geassisteerde fiberoptische intubatie techniek. Het F4L-lichaamsmodel kreeg een ruime score voor realisme als moeilijk luchtwegmodel (7.6). Wij meenden, de limitaties van het onderzoek in acht nemend, voorzichtig te kunnen concluderen dat de videolaryngoscopisch geassisteerde

7

fiberoptische intubatie techniek tot een hoger intubatiesucces kan leiden. Gezien het hogere percentage aan zicht op de toegang tot de luchtpijp die de deelnemers rapporteerden, leek dit ons plausibel.

De belangrijkste conclusies van dit proefschrift die genoemd worden in **hoofdstuk 6** zijn:

1. Het F4L-lichaamsmodel kan een geschikt en realistisch alternatief zijn voor het synthetisch luchtwegmodel, en dan met name voor de kapbeademing.
2. Het F4L-lichaamsmodel is een geschikt en realistisch model voor het leren van geavanceerde luchtwegtechnieken, te weten videolaryngoscopie en de flexibele laryngo-tracheoscopie.
3. Het F4L-lichaamsmodel is een geschikt en realistisch model voor het leren van het identificeren van het ligamentum cricothyroideum door middel van palpatie en met behulp van de echo.
4. Het hogere percentage aan zicht op de toegang tot de luchtpijp verkregen met de videolaryngoscopisch geassisteerde fiberoptische intubatie techniek ten opzichte van videolaryngoscopie alleen, leidt waarschijnlijk tot een hoger intubatiesucces in een moeilijke luchtweg.

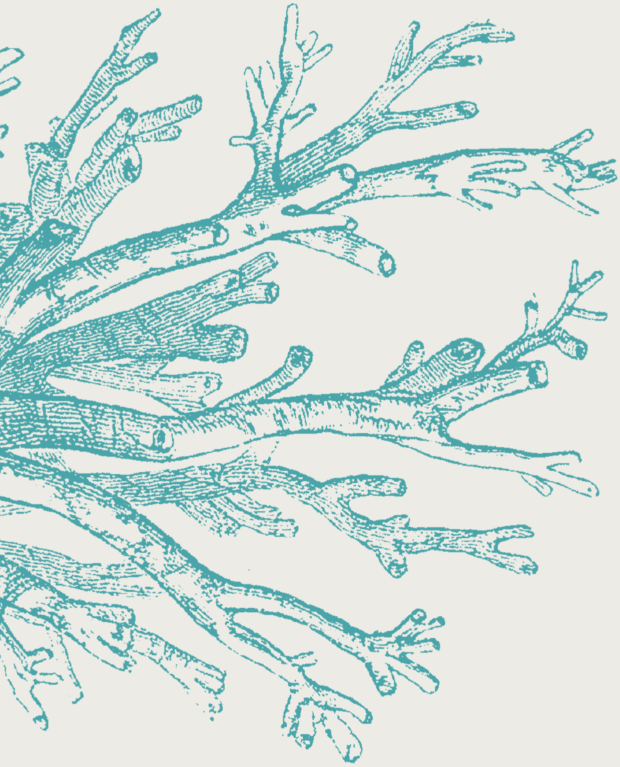
Alhoewel er aanwijzingen zijn dat trainees meer vertrouwen krijgen en aangeven een betere leerervaring te beleven wanneer zij vaardigheden leren op lichaamsmodellen, moet de translationele waarde van het leren van procedurele vaardigheden op lichaamsmodellen nog definitief aangetoond worden. Voor het onderhouden van reeds aangeleerde vaardigheden voor procedures die niet vaak in praktijk nodig zijn, kan een lichaamsmodel zoals het F4L-lichaamsmodel wellicht een realistische en geschikte uitkomst bieden.

Beperkingen van het F4L-lichaamsmodel zijn de relatief vaak hoge leeftijd van de lichaamsdonoren bij overlijden, waardoor het lichaamsmodel wellicht niet altijd vergelijkbaar is met de jongere patiënt. De kosten voor het in stand houden van een anatomische faciliteit, met daarbij personeel, vloeistoffen, logistiek e.d. zijn ook aanzienlijk. Daarbij brengt het werken met lichaamsmateriaal altijd gevaren met zich mee, waardoor ook altijd de nodige voorzorgsmaatregelen in acht moeten worden genomen. Sommige moderne synthetische modellen hebben de mogelijkheid om ademhaling en hartslag te simuleren. Dat is evident geen mogelijkheid in F4L-lichaamsmodellen, waardoor deze minder geschikt zijn voor trainingsscenario's waarin ook de actuele vitale parameters van de patiënt benodigd zijn voor het onderwijs.

Gezien het enorme arsenaal aan modellen, simulators en dergelijke dat reeds beschikbaar is op de markt, is het waarschijnlijk realistischer om het F4L-lichaamsmodel te beschouwen als aanvulling. Echter, voor het F4L-lichaamsmodel geldt dat de variatie in de anatomie die je aan kunt treffen van lichaam tot lichaam (bijvoorbeeld ook obesitas) en de mogelijkheid tot het doen van invasieve en echogeleide procedures, wellicht leiden tot nog meer mogelijkheden voor training. Vanuit het perspectief van de anatoom is het interessant te onderzoeken hoe het F4L-lichaamsmodel nog meer in te zetten is in postacademisch onderwijs, zodat door zo veel mogelijk (toekomstig) medische professionals optimaal gebruik kan worden gemaakt van de grote gift die lichaamsdonoren geschonken hebben.

APPENDICES

Co-authors and affiliations
Dankwoord
Curriculum vitae



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